

# i-CAT<sup>®</sup> Technical Guide



Cone Beam 3D +  
2D Panoramic Dental  
Imaging System



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# TABLE OF CONTENTS

## **Chapter 1 - Introduction**

i-CAT FLX Description .....	1-1
Operator Control Box .....	1-2
Patient Emergency Stop Control .....	1-3
Software Description .....	1-3
SmartScan STUDIO Software .....	1-3
Tx STUDIO Treatment Planning Software .....	1-3
System Requirements .....	1-4

## **Chapter 2 - Startup and Shutdown**

Scanner Startup .....	2-1
Power Up .....	2-1
Log in .....	2-1
Scanner Shutdown .....	2-2
Log out .....	2-2
Power Off .....	2-2
Cycle Scanner Power .....	2-2

## **Chapter 3 - Calibrations and Quality Assurance**

Run Calibration and QA Tests .....	3-1
Panel Calibration .....	3-2
Run Panel Calibration .....	3-2
Panel Calibration Failure .....	3-2
Shutter Calibration .....	3-3
Run Shutter Calibration .....	3-3
Shutter Calibration Failure .....	3-3
Geometric Calibration .....	3-4
Install Geometric Calibration Fixture .....	3-4
Run Geometric Calibration .....	3-4

QA Line Pair Test .....	3-5
Setup QA Phantom .....	3-5
Run QA Line Pair Test .....	3-6
QA Line Pair Evaluation .....	3-7
Distance Measurement Test .....	3-9
QA Material Test .....	3-10
Set Up QA Phantom .....	3-10
Run QA Material Test .....	3-10
QA Material Evaluation .....	3-11
QA Air Water Test .....	3-14
Set Up QA Air Water Phantom .....	3-14
Run QA Air Water Test .....	3-14
QA Air Water Test Evaluation .....	3-15
QA PAN Test .....	3-21
Install PAN Phantom .....	3-21
Run QA PAN Test .....	3-22
QA PAN Test Evaluation .....	3-22
Radiation Output Test .....	3-23
Measured Dose .....	3-23
Interpretation .....	3-24

## **Chapter 4 - Site Administration**

Site Administrator Account .....	4-1
Configurator .....	4-1
Accounts .....	4-2
Institution .....	4-3
Network .....	4-3
Maintenance .....	4-3
Dose LogBook .....	4-3
Device Activity Log .....	4-4
Regular Backups of Image Data .....	4-4

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**Chapter 5 - Data Utilities**

Introduction .....	5-1
FLX Data Utility .....	5-1
Install and Configure FLX Data Utility .....	5-2
Using the FLX Data Utility .....	5-3
Export FLX Database to DEXIS Database .....	5-8
FLX Patient Data Utility .....	5-8
Install and Configure FLX Patient Data Utility .....	5-9
Using the FLX Patient Data Utility .....	5-10

**Appendix A - Safety Information**

Important Safety Information .....	A-1
Electrical Hazards .....	A-3
Explosion Hazard .....	A-3
Mechanical Hazards .....	A-3
Collision System .....	A-3
Tube Head Leakage .....	A-4
Laser Beam Hazards .....	A-4
Radiation Safety .....	A-4
Radiation Protection Measures .....	A-5
Safety Devices .....	A-5
Emergency Stops .....	A-5
Warning System .....	A-5
Interlock System .....	A-6
Site Layout .....	A-6
Cabling Requirements .....	A-6

**Appendix B - Product Information**

Essential Performance .....	B-1
User Proficiency .....	B-1
Service .....	B-2
Technical Specifications .....	B-3
Power Requirements .....	B-4
Apparent Resistance of Supply Mains .....	B-4
Weight .....	B-5

Patient Support Chair .....	B-5
Environmental Specifications .....	B-5
Operating .....	B-5
Transportation and Storage .....	B-5
Labels .....	B-6
Proper Disposal of Electronic Equipment .....	B-15
Product Disposal .....	B-15
Passing the Product on to Another User .....	B-16
Scanner Dimensions .....	B-17
Preventive Maintenance Schedule - for Owner / User .....	B-18
Cleaning .....	B-18
Planned Maintenance - 12 Month Schedule .....	B-19
Planned Maintenance Checklist .....	B-19
Replaceable Parts .....	B-20
Supplemental Components .....	B-21
PAN Scan Components .....	B-23
Equipment Standards .....	B-24
Equipment Class .....	B-24
Equipment Cables .....	B-24
Manufacturer's Declaration .....	B-25
Acknowledgements .....	B-32

## **Appendix C - Radiation Information**

Recommended Operating Requirements .....	C-1
Scan Times and Settings .....	C-2
Scatter Radiation .....	C-2
Conditions of Operation .....	C-2
Patient Dose .....	C-11
Dose and Sensitivity Profile .....	C-12
Detective Quantum Efficiency (DQE) .....	C-13
X-ray Tube Assembly .....	C-14

# **Chapter 1 Introduction**

## ***i-CAT FLX Description***

The i-CAT® FLX™ is a Cone Beam Volumetric Tomography and Panoramic scanner used for dental head and neck applications. It consists of a scanner, scanner controller, touch screen and keyboard which is suitable for an in-office environment.



**i-CAT® FLX™ with Touch Screen**

The scanner is an open design that allows patients to sit upright during a procedure. An electric powered seat is built into the scanner for proper patient positioning. The scanner captures data for 3D skull reconstruction for the following procedures:

- Implants
- TM Joints
- Reconstructed Panoramic
- Reconstructed Cephalometrics
- Airway / Sinus, etc.
- Nerve Canal
- PAN - Optional Conventional Digital Panoramic Feature

Cone Beam Volumetric Tomography is a medical imaging technique that uses X-rays to obtain cross-sectional images of the head or neck. Quality of the images depends on the level and amount of X-ray energy delivered to the tissue. Imaging displays both high-density tissue, such as bone, and soft tissue. When interpreted by a trained physician, these images provide useful diagnostic information.

## ***Operator Control Box***

The operator control box must be located outside of the patient environment, and can be placed on a desktop or wall-mounted. The site layout must provide a means for audio and visual communication between the operator and patient during scanning.

**ON** powers the scanner and the POWER indicator lights to show that the scanner is ON.

**OFF** removes power from the scanner and the POWER indicator goes OFF.

**SCAN** initiates patient X-ray scanning.

**EMERGENCY STOP** immediately halts all X-ray and scanning activities.

**NOTE:** The following indicators are also located on the scanner overhead.

**POWER** indicator is lit when the scanner is ON.

**READY** indicator is lit when a scan is initiated and the scanner is ready to scan. If the optional deadman handswitch is installed, this indicator will flash to alert the operator to press the handswitch.

**X-RAY** indicator is lit during X-ray exposure.

**FAULT** indicator lights when a scanner error occurs, such as an X-ray exposure problem or early release of the optional deadman handswitch.



### ***Patient Emergency Stop Control***

The emergency stop control allows the patient to halt all X-ray and scanning activities by pressing the button.

The emergency stop control can either be hung from the head support mechanism or held in the patient's hand as desired.



## ***Software Description***

### ***SmartScan STUDIO Software***

SmartScan STUDIO software is used for taking scans on the i-CAT FLX and runs on the scanner controller. SmartScan STUDIO Manager software is used to enter patient data and access patient studies. It is loaded on a clinical workstation. Optionally, your site may choose to use DEXIS software, instead of SmartScan STUDIO Manager, for patient administration.

### ***Tx STUDIO Treatment Planning Software***

Tx STUDIO™ treatment planning software reconstructs 3D volume rendering from images acquired on the i-CAT FLX. Tx STUDIO is offered for exclusive use with the i-CAT imaging system, which is manufactured by Imaging Sciences. Tx STUDIO may not be available in all regions.

## System Requirements

i-CAT recommends that all computer systems meet the following specifications. Computer systems not meeting the specifications may have performance impacts.

**NOTE:** For workstations running Tx STUDIO, refer to the Tx STUDIO Reference Manual for additional system requirements.

Item	System Requirements
<b>CPU</b>	Intel® Dual Core 2.0 GHz or higher
<b>Mother Board</b>	Intel® and VIA® PCI Bus chipsets
<b>Operating System</b>	<u>Server Only:</u> Windows® 7 Professional, Ultimate, and Enterprise (64-bit) SP1 Windows® 8 Pro and Enterprise (64-bit) Windows® Server 2008 R2 SP1 (make sure .NET 3.5.1 is enabled before loading software)
	<u>Client-Server or Client workstation:</u> Windows® 7 Professional, Ultimate, and Enterprise (64-bit) SP1 Windows® 8 Pro and Enterprise (64-bit)
	<b>Note:</b> <i>Dedicated file servers above are recommended in networks with more than 5 imaging workstations.</i>
<b>System Memory</b>	4 GB or larger
<b>Hard Disk Drive</b>	1 TB or larger
<b>Graphics Card</b>	NVidia with 512 MB RAM
<b>Monitor</b>	21" high resolution widescreen LCD with a contrast ratio of 10,000:1 or better
	<b>Note:</b> <i>LCD monitors should be used in native resolution, and must display all shades of gray accurately.</i>
<b>USB</b>	USB 2.0
<b>Network Card</b>	1000 baseT network cards
	<b>Note:</b> <i>Wireless networks are not recommended.</i>
<b>DVD Drive</b>	16x or higher
<b>Internet Connection</b>	High-speed internet connection required for software updates and remote diagnostics (1 GB recommended)
	<b>Note:</b> <i>The scanner controller is a machine-control computer and is not configurable. The 1 GB Ethernet port can be configured for use with a server.</i>

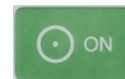
# Chapter 2 *Startup and Shutdown*

## **Scanner Startup**

The scanner and scanner controller are powered independently. Both must be on to function properly and are available for use immediately after startup. No warm up is required.

### **Power Up**

1. **Power up the scanner:** press the ON button on the operator control box. The POWER indicator on the operator control box and scanner should light.
2. **Power up scanner controller and touch screen:** press the power button on the front of the scanner controller. The log in screen is displayed.




### **CAUTION**

If the scanner or the scanner controller is powered off, at scanner power up or scanner controller boot up, when the first scan is initiated (scout or full scan), the i-CAT FLX performs a reset procedure that may delay the start of first scan.

### **Log in**

Two log in account types are available for site use. The site administrator will assign the account type to site personnel. A typical user will log in directly to SmartScan STUDIO. A site administrator log in account accesses an administration menu. Refer to *Site Administration* for information.




To log in to SmartScan STUDIO on the scanner controller:

1. Enter your user name and password.
2. Press  to log in.


**NOTE:** Refer to the *i-CAT FLX User Manual* for information about using SmartScan STUDIO for the scanning workflow.

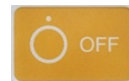
## Scanner Shutdown

### Log out

1. Press . This button is accessible from Scheduled Exams or at the conclusion of the scanning workflow.
2. On the logout confirmation dialog, press  to close exam and log out.
3. Depending on your account type, either the User menu or the Administrator menu is displayed.
4. Press  to log out of SmartScan STUDIO. The log in screen is displayed.

### Power Off

1. **Power off scanner:** Press the OFF button on the operator control box. The scanner shuts down and the POWER indicators on the operator control box and scanner go OFF.
2. **Power off scanner controller and touch screen:** Press power button on the touch screen to power off both the touch screen and scanner controller. On the shutdown confirmation dialog, press  to shutdown.



### Cycle Scanner Power

If at any time the Ethernet cable connecting the scanner to the scanner controller becomes disconnected, reconnect the cable and cycle the power to the scanner from the circuit breaker at the rear of the scanner overhead.



Ethernet Cable



Power Circuit Breaker

# Chapter 3 Calibrations and Quality Assurance

## Run Calibration and QA Tests

Options for running scanner tests are available on the Utilities menu.

From SmartScan STUDIO scanning workflow, press  to access the Utilities menu.

**NOTE:** Refer to the *i-CAT FLX User Manual* for information about using SmartScan STUDIO for the scanning workflow.

Option	Description
PanelCal	Panel calibration should be performed once a week.
ShutterCal	Shutter calibration should be performed once a week to ensure optimal image quality.
ChairCal	Chair calibration is to be performed by Service Technicians only.
GeoCal	Geometric calibration should be performed once a year to ensure optimal image quality. Run as needed if the image quality is degraded.
QA Line Pair	QA Line Pair test checks the spatial resolution using the QA phantom.
QA Material	QA Material test checks consistency of measurements in various materials using the QA phantom.
QA Air Water	QA Air Water test is a noise level and uniformity test. HU measurements are taken at five different regions within the water volume of the water phantom.
QA Pan	QA Pan test is used to validate the PAN scan data capture using the PAN phantom.
Reprocess Exam	Refer to <i>i-CAT FLX User Manual</i> for information.
Favorites Manager	Refer to <i>i-CAT FLX User Manual</i> for information.
Roll-off	Roll-off is to be used by Service Technicians and other qualified personnel only.



## CAUTION

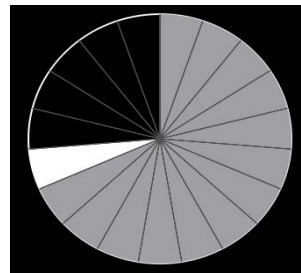
If the optional deadman handswitch is installed on the scanner, press and hold handswitch before pressing the **Scan** button, and continue to hold handswitch down for the duration of the exposure (**X-ray** light on). Early release of the handswitch stops the exposure and the **Fault** light turns on. The patient will have to be re-scanned.

---


## Panel Calibration

It is recommended that Panel Calibration be performed once a week.


PanelCal is performed in both landscape and portrait positions for 4 x 4 and 2 x 2 resolutions. Several tests run as part of the panel calibration. A pie chart displays status.



### Run Panel Calibration

1. From Utilities menu, select **PanelCal**.
2. Ensure the field of view on the scanner is clear.
3. Press . The scanner initializes.
4. When prompted, press the **Scan** button on the operator control box. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.
5. You will be prompted to press the **Scan** button for each test.


**NOTE:** The panel will rotate to the portrait position at the start of the portrait tests.

6. When Panel Cal is complete, **Calibration Complete** is displayed.
7. Press  to display Complete screen and select another option.

### Panel Calibration Failure

If the calibration fails, the following message is displayed:

#### Panel Calibration Processing Failure

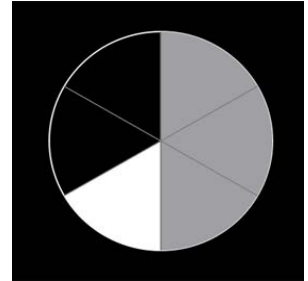
Press  to exit.

Check that the field of view is clear of all objects and that there are no obstacles to the rotation of the gantry. Re-run PanelCal. If failure persists, contact Technical Support.



## Shutter Calibration

It is recommended that Shutter Calibration be performed once a week to ensure optimal image quality. This calibration is also necessary if a mechanical adjustment is made to the beam limiter or if image quality has degraded.

ShutterCal runs several tests in both landscape and portrait positions. A pie chart displays status.



### Run Shutter Calibration

1. From Utilities menu, select **ShutterCal**.
2. Ensure the field of view on the scanner is clear.
3. Press . The scanner initializes.
4. When prompted, press the **Scan** button on the operator control box. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.
5. You will be prompted to press the **Scan** button for each test.  
**NOTE:** The panel will rotate to the portrait position at the start of the portrait tests.
6. When Shutter Cal is complete, **Calibration Complete** is displayed. Thumbnail images of each Shutter Cal test are available to view.
7. If desired, select a thumbnail to view.
8. Press  to display Complete screen and select another option.

### Shutter Calibration Failure

If the calibration fails, the following message is displayed:

#### Shutter Calibration Processing Failure

Press  to exit.

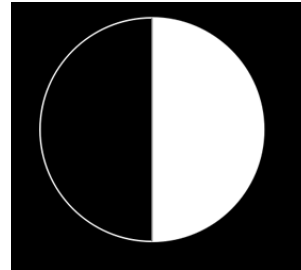
Check that the field of view is clear of all objects and that there are no obstacles to the rotation of the gantry. Re-run ShutterCal.

If failure persists, contact Technical Support.

## Geometric Calibration

It is recommended that Geometric Calibration be performed once a year to ensure optimal image quality or if the image quality is degraded.

GeoCal runs in both portrait and landscape positions. A pie chart displays status.





### Install Geometric Calibration Fixture

1. Mount the phantom platform and center the GeoCal fixture on the platform using the alignment holes on the bottom of fixture.
2. Ensure that the GeoCal fixture is level.
3. Using the Alignment Lasers, align the GeoCal fixture crosshair slits with the laser cross beams. The laser beams should roughly align with the fixture crosshair slits.



### Run Geometric Calibration

**NOTE:** If you get the message “Geometric Calibration Processing Failure” during this procedure, contact Technical Support.

1. From Utilities menu, select **GeoCal**.
2. Verify GeoCal fixture installation, then press . The scanner initializes.
3. When prompted, press the **Scan** button on the operator control box. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.
4. When landscape calibration completes, the message **Step 1 Complete** is displayed.
5. Press  to initiate portrait calibration. The panel rotates.
6. When prompted, press the **Scan** button on the operator control box. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.
7. When portrait calibration completes, the message **Step 2 Complete** is displayed.

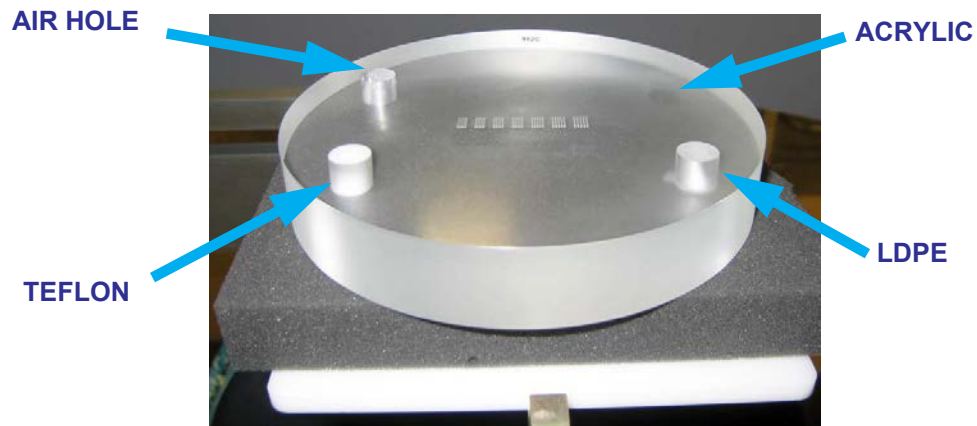


8. Press  to display Complete screen and select another option.

## QA Line Pair Test

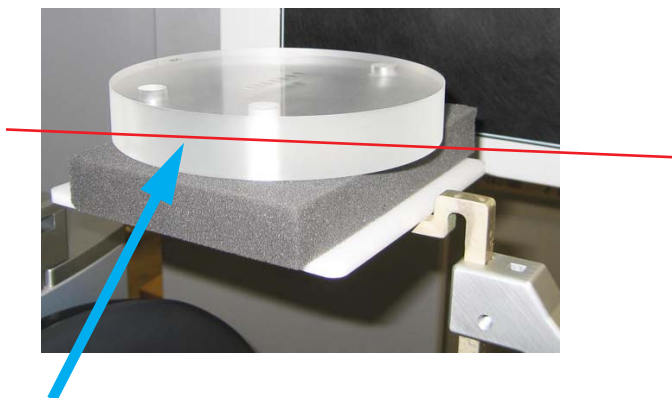
### Setup QA Phantom

1. Remove chin cup and insert phantom platform.
2. Place QA phantom on platform. Use a piece of foam beneath the phantom to elevate it. Make sure phantom is level.
3. Center the QA phantom on the platform with the air hole positioned at the left rear of the gantry. The embedded metal strips should align left to right.






4. Using the Alignment Lasers, adjust the platform height so that the horizontal laser is positioned at the center of the QA phantom.

Make sure the phantom is centered left to right and front to back. Use the lasers to confirm.





**Horizontal Laser Line  
through Center of Phantom**

### ***Run QA Line Pair Test***


1. From Utilities menu, select **QA Line Pair**.
2. Ensure phantom is set up properly, then press  .
3. Select  , then press  . The scanner initializes.
4. When prompted, press the **Scan** button on the operator control box. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.
5. Review the scout image. The phantom must be centered and level. Adjust the phantom platform as needed to achieve the proper height.
6. To move the phantom to the right or left, use the **Front/Back** slider control.

If required, make adjustments, then press  to run  again. Repeat as required until phantom is properly aligned.

7. When phantom is aligned, select  and press  .

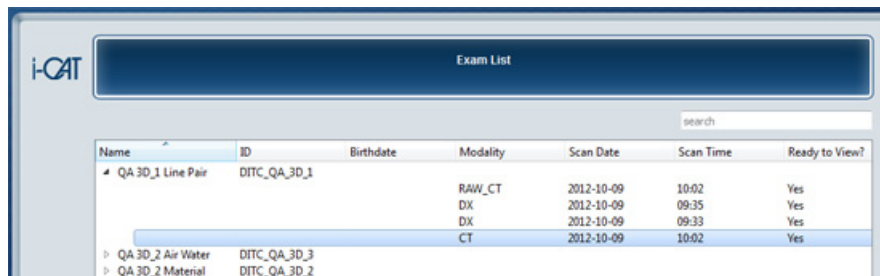
- When prompted, press the **Scan** button on the operator control box. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.

The scanner acquires data and a status indicator shows acquisition and image creation progress. When image processing is complete, image is displayed.

- Review image to ensure adequate quality. Press  to display Complete screen and select option to go Back to Utility.

## QA Line Pair Evaluation

- At a clinical workstation, start SmartScan STUDIO Manager and select **Exam List**.
- On Exam List, locate QA 3D\_1 Line Pair exam with most current date. Double-click CT entry to load study in Tx STUDIO.

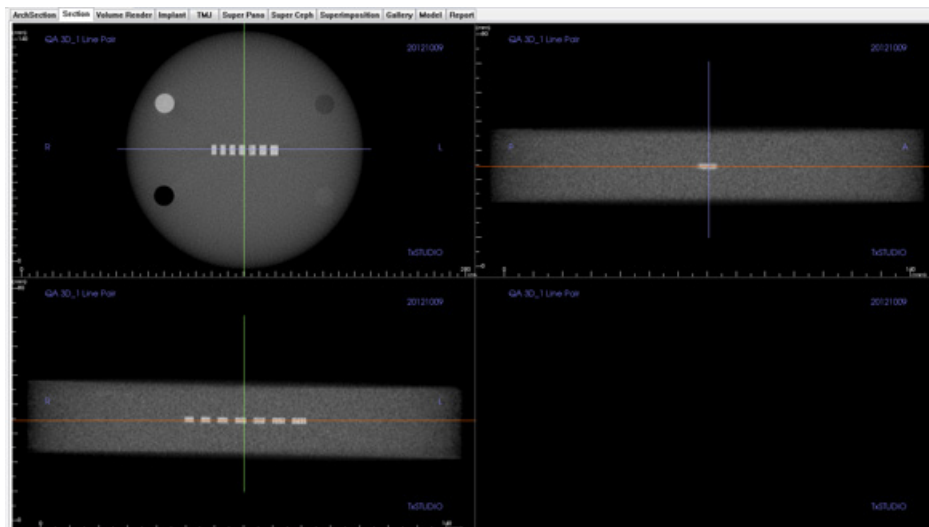


Name	ID	Birthdate	Modality	Scan Date	Scan Time	Ready to View?
QA 3D_1 Line Pair	DITC_QA_3D_1		RAW_CT	2012-10-09	10:02	Yes
			DX	2012-10-09	09:35	Yes
			DX	2012-10-09	09:33	Yes
			CT	2012-10-09	10:02	Yes
QA 3D_2 Air Water	DITC_QA_3D_3					
QA 3D_2 Material	DITC_QA_3D_2					


**NOTE:** If a pop-up message displays stating “Tru-Pan failed to process”, click **OK** and continue.

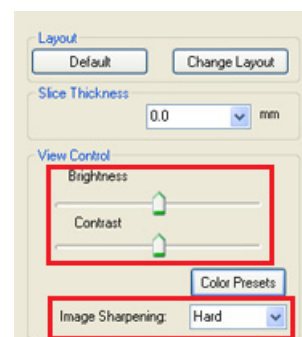
- When exam is loaded, select **Section** tab at top of display.

4. In the upper right corner view, click where the vertical and horizontal cursor lines cross and drag to the center of the line pairs, as shown below.

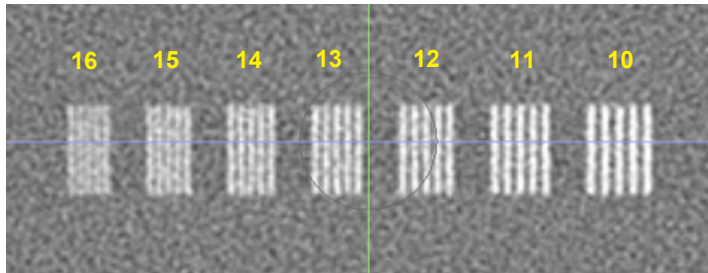


5. Zoom upper left line pair image. To zoom, move the mouse cursor in the center of the image, hold down the Control key and press the left mouse button. Move the cursor up or down to zoom in or out as needed.
6. Select **Image Sharpening > Hard**.
7. Adjust Brightness and Contrast levels for the best viewing of line pairs.

**NOTE:** To better view image, select  to turn off cursor lines.





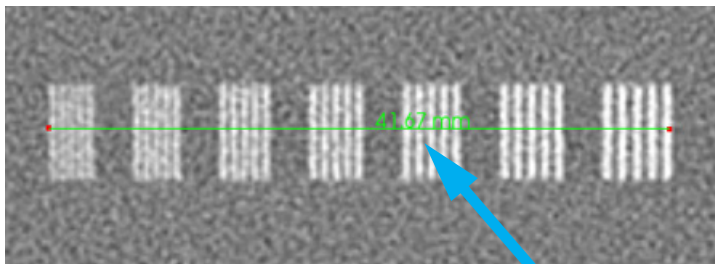
8. Evaluate the image. Line Pairs 10 through 16 are displayed in the image.
9. Verify that definition is present within line pairs 10, 11, and 12. Compare image quality to the image shown below.



### ***Distance Measurement Test***

To ensure measurement accuracy, this procedure checks Distance measurements.

1. Select  to activate Distance tool.  
**NOTE:** To better view image, select  to turn off cursor lines.
2. Click on the outside line of set 16, and then click on the outside line of set 10 to draw a line, as shown below.



**Distance Line**




3. The measurement should be between 41 and 42 mm.
4. When finished, close Tx STUDIO.


## QA Material Test



### Set Up QA Phantom

Follow steps in [Setup QA Phantom](#), if phantom is not already in place.


### Run QA Material Test

1. From Utilities menu, select **QA Material**.
2. Ensure phantom is set up properly, then press .
3. Select , then press . The scanner initializes.
4. When prompted, press the **Scan** button on the operator control box. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.
5. Review the scout image. The phantom must be centered and level. Adjust the phantom platform as needed to achieve the proper height.
6. To move the phantom to the right or left, use the **Front/Back** slider control.

If required, make adjustments, then press  to run  again. Repeat as required until phantom is properly aligned.

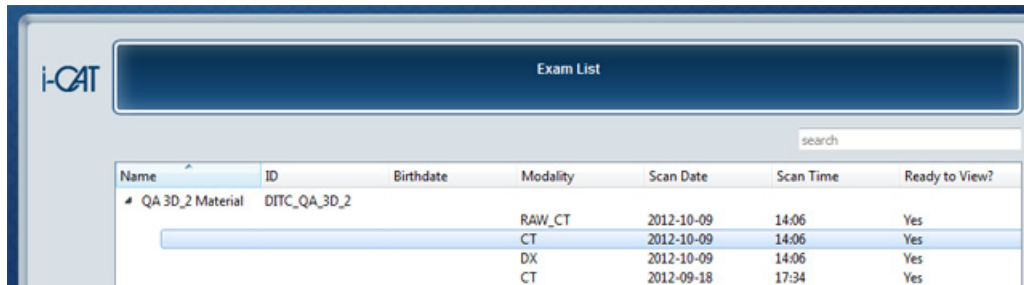
7. When phantom is aligned, select  and press .
8. When prompted, press the **Scan** button on the operator control box. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.

The scanner acquires data and a status indicator shows acquisition and image creation progress. When image processing is complete, image is displayed.

9. Review image to ensure adequate quality. Press  to display Complete screen and select option to go Back to Utility.

## QA Material Evaluation

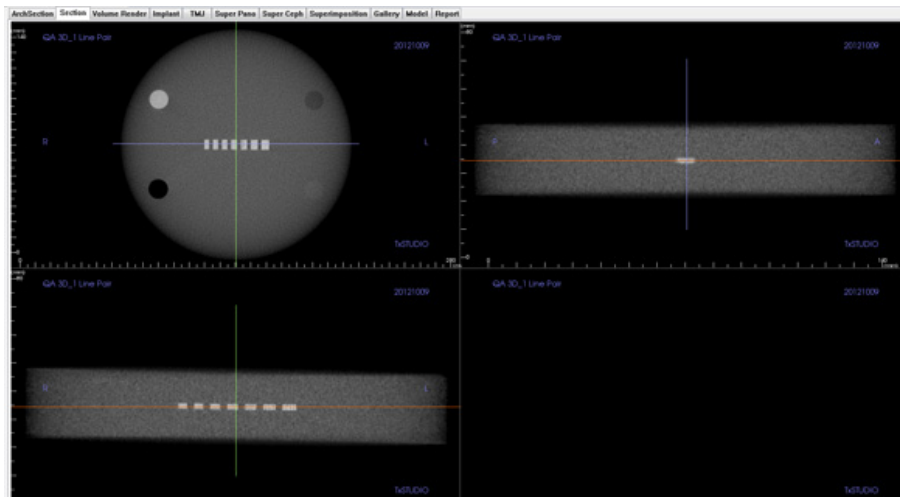
1. At a clinical workstation, start SmartScan STUDIO Manager and select **Exam List**.
2. On Exam List, locate QA 3D\_2 Material exam with most current date. Double-click CT entry to load study in Tx STUDIO.



Name	ID	Birthdate	Modality	Scan Date	Scan Time	Ready to View?
QA 3D_2 Material	DITC_QA_3D_2		RAW_CT	2012-10-09	14:06	Yes
			CT	2012-10-09	14:06	Yes
			DX	2012-10-09	14:06	Yes
			CT	2012-09-18	17:34	Yes

**NOTE:** If a pop-up message displays stating “Tru-Pan failed to process”, click **OK** and continue.

3. When exam is loaded, select **Section** tab at top of display.
4. In the upper right corner view, click where the vertical and horizontal cursor lines cross and drag to the center of the line pairs, as shown below.





5. Zoom upper left image. To zoom, move the mouse cursor in the center of the image, hold down the Control key and press the left mouse button. Move the cursor up or down to zoom in or out as needed.

6. Select **Image Sharpening > Normal**.

7. In Slice Thickness, enter 0.4 (mm).

8. Adjust Brightness and Contrast levels for the best viewing of material areas.

9. Select  to activate HU tool.


**NOTE:** To better view measurements, select  to turn off display information.



10. Draw a box with an area of at least 40mm<sup>2</sup> but less than 46mm<sup>2</sup> in the center of each circle of the four material areas in the phantom image.

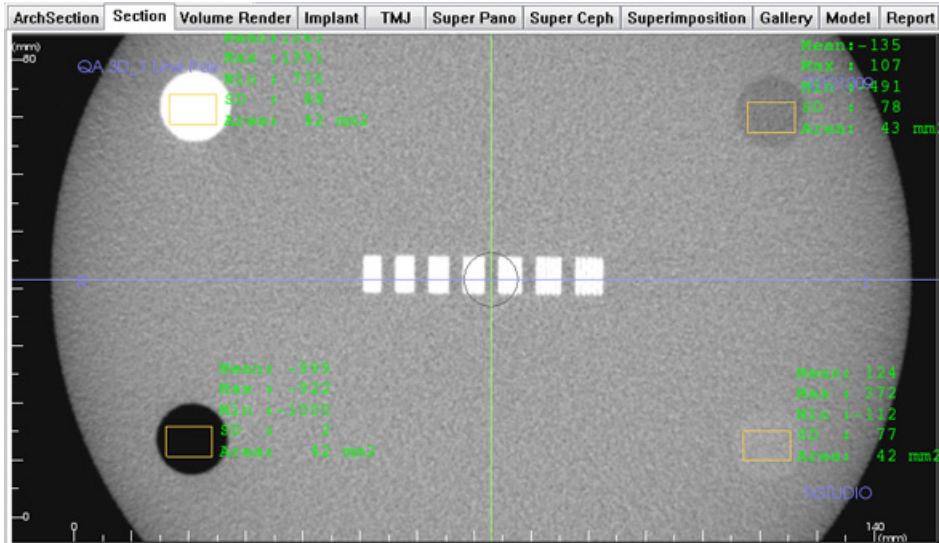
**NOTE:** The dimension of each measurement is very important. Be consistent for each assessment to achieve the minimum deviation.

- a. Click and release at starting point. A red circle displays.
- b. Move cursor to draw box.
- c. When correct area is displayed (40mm<sup>2</sup> but less than 46mm<sup>2</sup>), click to set box and display HU information.

**NOTE:** To remove a measurement, click the measurement to select it, the press **Delete** on the keyboard. When measurements are removed, you will need to select  to re-activate HU tool



- d. Repeat for remaining material areas. Try to make each box as close in size as possible.



11. Record the Mean HU value of each material. See table below. Recorded values should fall within the lower and upper limits.

Material	Mean Scan Value (Hounsfield Units)	Lower Limit	Upper Limit	Mean
<b>Air</b> (Black) (lower left)		-1000	-980	-990
<b>Acrylic</b> (Light Gray) (lower right)		-50	200	75
<b>LDPE</b> (Dark Gray) (upper right)		-250	-50	-150
<b>Teflon</b> (White) (upper left)		580	1160	870

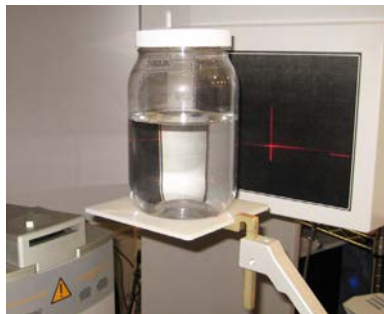
12. When finished, close Tx STUDIO.

## QA Air Water Test




### Set Up QA Air Water Phantom

**NOTE:** It is important to use the water phantom provided with the scanner. Use distilled water in the phantom. Using tap water may negatively affect the test results.



1. Remove chin cup and insert phantom platform at lowest position.
2. Fill phantom half full with distilled water and carefully place on platform.
3. Using the Alignment Lasers, center the water bath with the horizontal laser across the center of the water depth.



### Run QA Air Water Test


1. From Utilities menu, select **QA Air Water**.
2. Ensure phantom is set up properly, then press .
3. Select , then press . The scanner initializes.
4. When prompted, press the **Scan** button on the operator control box. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.
5. Review scout image. The phantom must be centered. Adjust the phantom platform as needed to achieve the proper height.
6. To move the phantom to the right or left, use the **Front/Back** slider control.

If required, make adjustments, then press  to run  again. Repeat as required until phantom is properly aligned.

7. When phantom is aligned, select  and press .

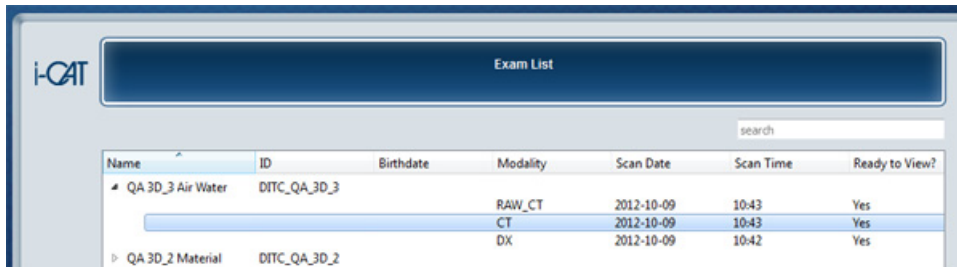
8. When prompted, press the **Scan** button on the operator control box. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.

The scanner acquires data and a status indicator shows acquisition and image creation progress. When image processing is complete, image is displayed.

9. Review image to ensure adequate quality. Press  to display Complete screen and select option to go Back to Utility.

## QA Air Water Test Evaluation

1. At a clinical workstation, start SmartScan STUDIO Manager and select **Exam List**.
2. On Exam List, locate QA 3D\_3 Air Water exam with most current date. Double-click CT entry to load study in Tx STUDIO.



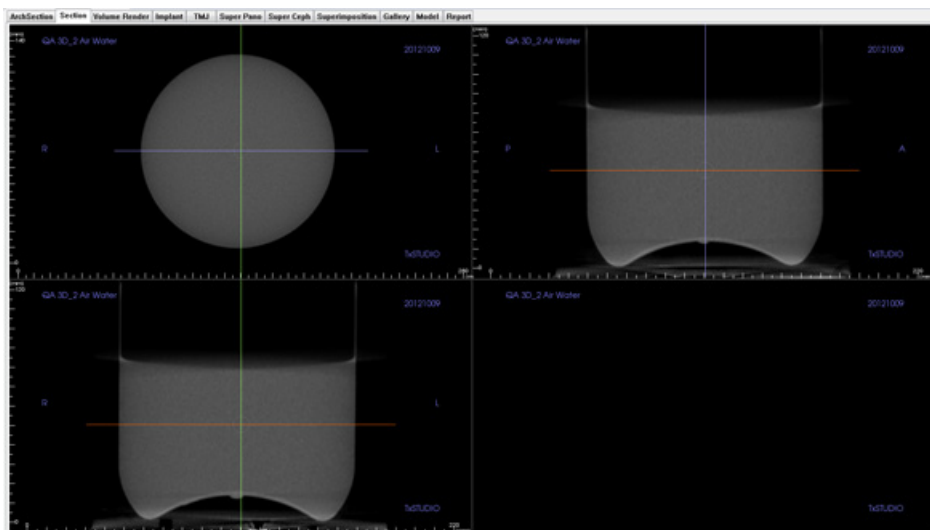
The screenshot shows the 'Exam List' window in the i-CAT software. It features a search bar at the top right. Below it is a table with the following columns: Name, ID, Birthdate, Modality, Scan Date, Scan Time, and Ready to View?. The table contains three rows of data. The first row is expanded, showing a sub-table with two rows: 'RAW\_CT' and 'CT'. The 'CT' row is highlighted in blue. The second row of the main table is 'QA 3D\_2 Material'.

Name	ID	Birthdate	Modality	Scan Date	Scan Time	Ready to View?
QA 3D_3 Air Water	DITC_QA_3D_3		RAW_CT	2012-10-09	10:43	Yes
			CT	2012-10-09	10:43	Yes
QA 3D_2 Material	DITC_QA_3D_2		DX	2012-10-09	10:42	Yes


**NOTE:** If a pop-up message displays stating “Tru-Pan failed to process”, click **OK** and continue.

3. When exam is loaded, select **Section** tab at top of display.

4. In the upper right corner view, click where the vertical and horizontal cursor lines cross and drag to the center of the water height and width, as shown below.

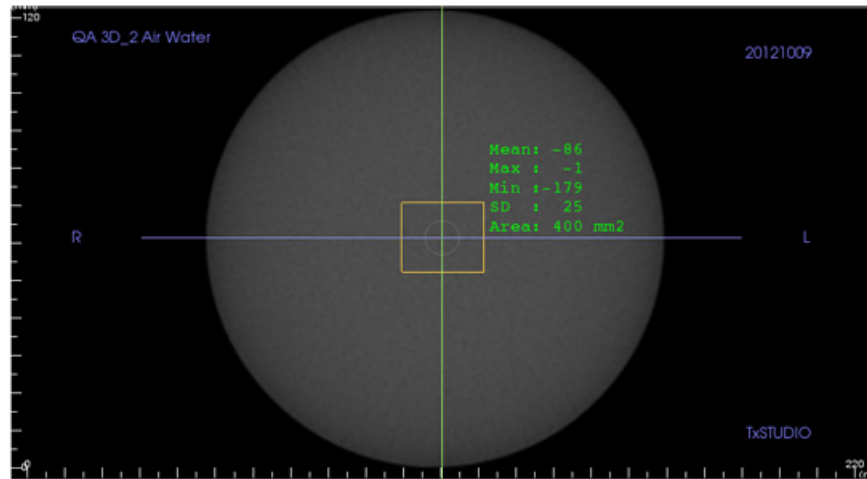



## Noise Level Evaluation

5. Zoom upper left image. To zoom, move the mouse cursor in the center of the image, hold down the Control key and press the left mouse button. Move the cursor up or down to zoom in or out as needed.
6. In Slice Thickness, enter 0.4 (mm).
7. Select  to activate HU tool.
8. Draw a box with an area of approximately 400 mm<sup>2</sup> in the center of the water in the phantom image, as shown below.
  - a. Click and release at starting point. A red circle displays.
  - b. Move cursor to draw box.

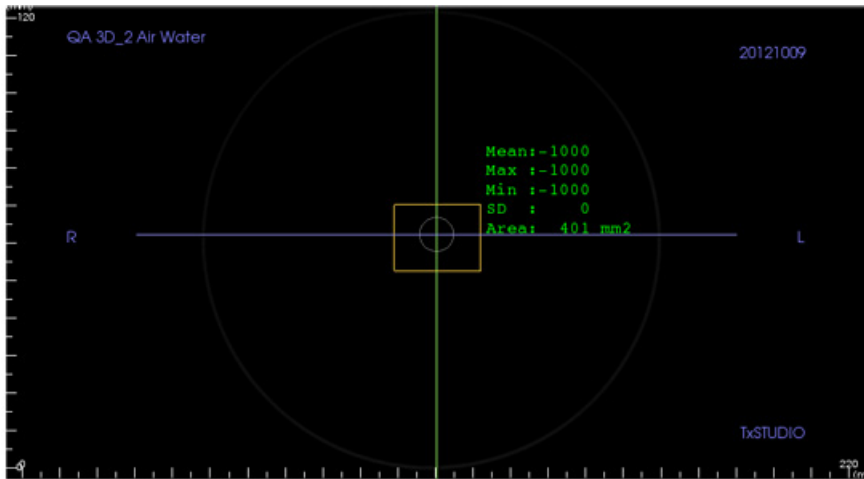


- c. When correct area is displayed (approximately 400 mm<sup>2</sup>), click to set box and display HU information.



9. Record the Water HU Mean value in the table below.
10. Remove measurement by clicking on it to select it, then press the **Delete** key on the keyboard.
11. In the upper right image, slide the vertical and horizontal cursor lines above the water level.
12. Select  to activate HU tool.
13. Draw a box with an area of approximately 400 mm<sup>2</sup> in the center of the water in the phantom image, as shown below.
  - a. Click and release at starting point. A red circle displays.
  - b. Move cursor to draw box.

- c. When correct area is displayed (approximately 400 mm<sup>2</sup>), click to set box and display HU information.



14. Record the Air HU Mean value in the table below. Recorded values should fall within the ranges.

Measured Values	Water	Air
Mean		
Expected Values	0 (-70 to +70)	-1000 (-1000 to -950)


15. Remove measurement by clicking on it to select it, then press the **Delete** key on the keyboard.


**NOTE:** Do not close image. This image is also used for the Uniformity Test.

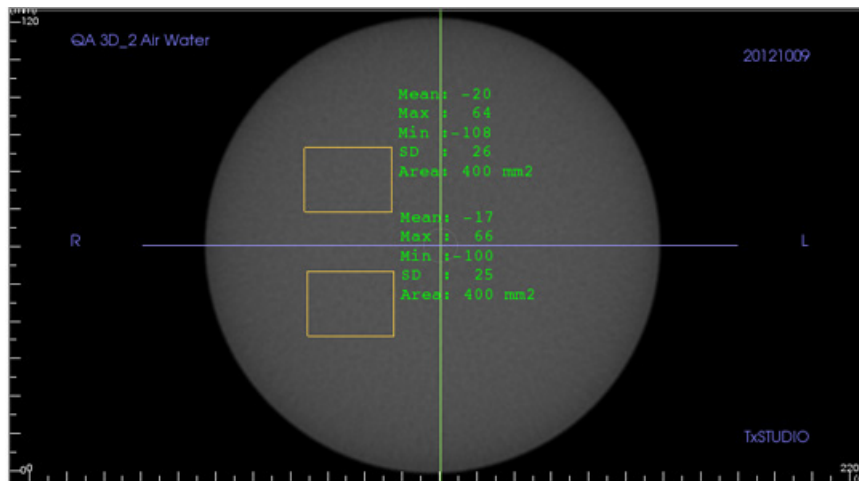
### ***Uniformity Evaluation***

The Uniformity test is used to check that image density measurements are consistent in all areas within the field of view.

16. In the upper right corner view, click where the vertical and horizontal cursor lines cross and drag to the center of the water height and width.

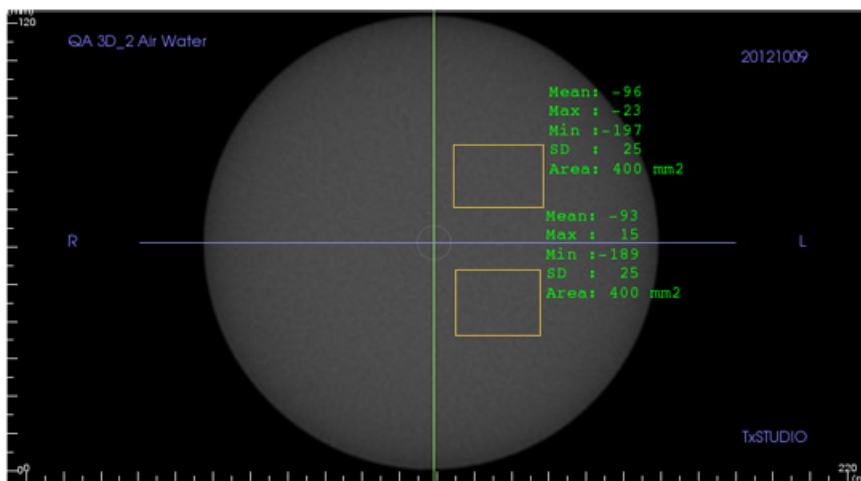
**NOTE:** To better view measurements, it may be necessary to select  to turn off display information.

17. Select  to activate HU tool.
18. Draw a box with an area of approximately 400 mm<sup>2</sup> in the upper left and lower left quadrants of the phantom image, as shown below.
  - a. Click and release at starting point. A red circle displays.
  - b. Move cursor to draw box.
  - c. When correct area is displayed (approximately 400 mm<sup>2</sup>), click to set box and display HU information.

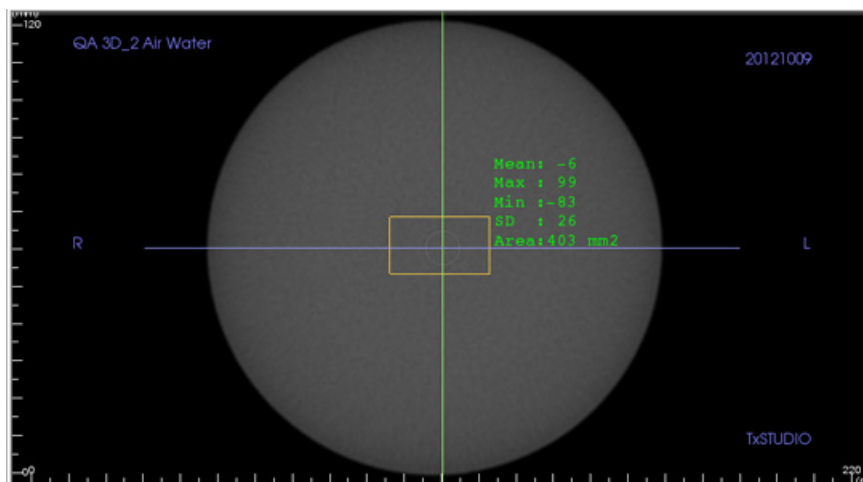


19. Record the Mean values in the chart below.
20. Remove measurements by clicking each one, then press the **Delete** key on the keyboard.

21. Repeat steps 17-20 for the upper right and lower right quadrants.



22. After recording values, a fifth measurement is required in the center of the water area. Repeat steps 17-20 for the water center.



23. Subtract each **Mean Value** from the **Mean Value** of the center measurement. If the difference is **greater than 90**, make sure phantom is correctly centered in the field of view and re-measure.



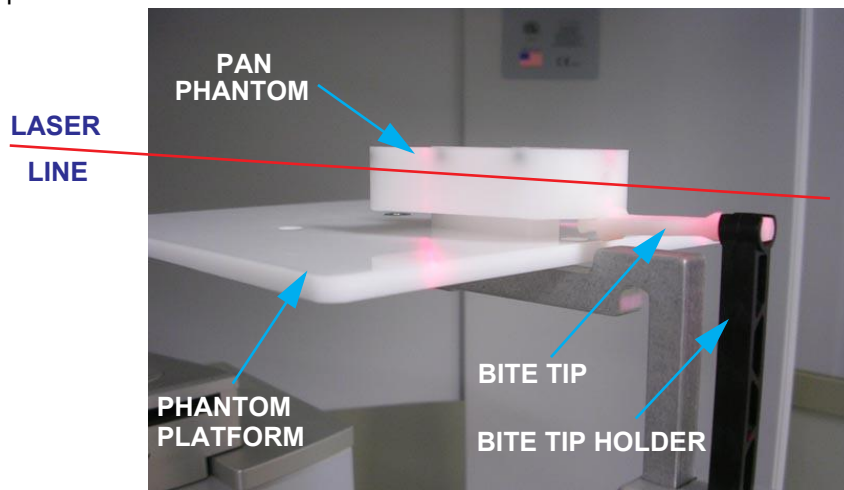
Measured Values	Upper Left	Upper Right	Lower Left	Lower Right	Center
Mean					

24. When finished, close Tx STUDIO.








## QA PAN Test

### Install PAN Phantom

1. Prepare the bite tip by inserting the narrow edges of the bite tip down into the bite tip holder uprights. Then turn the bite tip a  $\frac{1}{4}$  turn to lock into place.
2. Insert the phantom platform and bite tip holder into the positioning block. The bite tip should rest on top of the platform.
3. Place PAN phantom on platform with balls facing up and top of arch resting on bite tip.
4. Use the Alignment Lasers to position the phantom. Use the horizontal laser to adjust the height of the phantom as shown below. Use the vertical laser to center the phantom on the platform.



## Run QA PAN Test

1. From Utilities menu, select **QA PAN**.
2. Ensure phantom is set up properly, then press .
3. Select , then press . The scanner initializes.
4. When prompted, press the **Scan** button on the operator control box. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.
5. Review the scout image. Ensure the phantom is centered. Adjust the phantom platform as needed to achieve the proper height.  
If required, make adjustments, then press . Run  again until phantom is properly aligned.
6. When phantom is aligned, select  and press . The scanner initializes and moves approximately 1/8 rotation to the Home Position.
7. When prompted, press the **Scan** button on the operator control box. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.

The scanner acquires data and a status indicator shows acquisition and image creation progress. When image processing is complete, image is displayed.

## QA PAN Test Evaluation

1. Review image. Use brightness and contrast controls as needed to enhance image. All seven metal balls should be visible, as shown below.



Elongation of the metal balls indicate that the phantom is not in the middle of the focal

trough due to poor chair alignment. Ensure PAN phantom is set up properly and repeat test. If a good image cannot be obtained, contact your Technical Support.

2. Press  to display Complete screen and select an option.

## ***Radiation Output Test***

It is recommended that a check of the kVp(eff) and Radiation Output of the X-ray source be performed annually by a qualified Physicist.

The incident Absorbed Dose at the detector may be measured using a dosimeter. Tests are performed to assess output value and to check for tube output consistency and timer accuracy.

1. Attach a dosimeter to the detector such that the sensor is positioned where the vertical (coronal) and horizontal (axial) lasers intersect.
2. Perform a 16 cm diameter x 13 cm height scan, 8.9 second, 0.4 voxel and record time and dose from meter.

## ***Measured Dose***

The table below shows measurements performed on the detector for a landscape mode standard scan.

Tube Potential (kV)	120
Selected Scan Time (seconds)	8.9
Number of Frames	309
Approximate Exposure Time (seconds)	3.7
Measured Exposure at Detector (mR)	188
Measured Exposure at Detector / mAs (mR/mAs)	10.14
Measured Exposure at 1m (mR/mAs)	4.69
Measured Dose at 1m ( $\mu$ Gy/mAs)	41.07
Dose at Detector per Frame ( $\mu$ Gy/fr)	5.33
Tube Output ( $\mu$ Gy/mAs @ 1m)	41.07
Distance Source to Detector (cm)	68
Frame Time (seconds)	0.012
Conversion Factor for Absorbed Dose (R to Gy)	0.00876

## ***Interpretation***

1. The dose per frame at the detector may be calculated by:

Dose per frame at Detector = Dose at Detector / Number of Frames

Where Number of Frames = 309 for 8.9 second scan

= 619 for 26.9 second scan

2. The tube output per mAs may be normalized to 1m using the inverse square law for the purposes of assessing consistency of tube output:




Tube Output ( $\mu\text{Gy/mAs}$ ) =  $\frac{\text{Dose at Detector}}{\text{Displayed mAs}} \times (\text{Source to detector distance})^2$

Where Source to detector distance = 0.68m for the scanner.


# Chapter 4 Site Administration

## Site Administrator Account

The Site Administrator login account provides access to additional functions for site administration.

Option	Purpose	
Configurator	Add, edit or delete user accounts Add or enter institution name Enter or view network information Image data maintenance View and export dose logbook View and export activity log	
Technical Support	Access i-CAT Technical Support website.	
Remote Assistance	Access website for remote Helpdesk assistance.	

## Configurator

1. Select **Configurator** from menu.
2. To exit Configurator, press .

## **Accounts**

This option enables the system administrator to add, edit, or delete user accounts.

### **Add Accounts**

Use this option to add a new user account.

1. Press **Add** and complete the following:
  - Username - name for user account
  - Display Name - name displayed when user is logged in
  - Description - description of user account type
  - Password - user-selected password
  - Password confirmation - re-enter user password

2. Press **Create**.

**NOTE:** Press **X** to close window without saving changes.

### **Edit Accounts**

Use this option to edit user information and/or to reset a user password.

1. Select user account from Accounts list and press **Edit**.
2. Make changes to the following fields as needed: Display Name, Description.
3. Press **Save**.
4. To reset the password for the user account, complete the following:
  - Password
  - Password confirmation
5. Press **Set Password**.

**NOTE:** Press **X** to close window without saving changes.

## **Delete Accounts**

Use this option to delete user accounts that are no longer needed.

1. Select user account from Accounts list and press **Delete**.
2. Confirm deletion on confirmation dialog box.

## **Institution**

Use this option to enter or update the institution name and address. This information is displayed on patient exam images.

Enter name and address of institution and press **Save**.

## **Network**

Use this option to enter or update the scanner network configuration and review network information.

**NOTE:** If you use **Obtain automatically** options, select this option for both the IP address and DNS server address.

Select **Full network details** to display information about Windows® IP configuration, Ethernet adapter LAN connection, Ethernet adapter i-CAT connection and Tunnel adapter.

## **Maintenance**

Exam data is maintained on the scanner controller for a short period of time before it copied to remote storage (image server). Exam data that has been committed to remote storage is removed from the scanner controller automatically during routine maintenance, which runs automatically on a weekly basis.

**Run Maintenance Now** - Use this option to perform the scheduled routine maintenance immediately instead of at the regularly scheduled time.

## **Dose LogBook**

Use this option to export the dose logbook for a selected patient or all patients. The dose logbook provides an itemized list of date, time, modality, and DAP values for each patient exposure.

1. Enter a patient name or select **All Patients**. You can also scroll the list or use controls at the top of the list.
2. Select calendar icons to specify a starting and ending date range, or select **All History**.
3. Press **Export**. You can either view the log or save the file. To save the file, enter a name for the file and select a location to save it on the scanner controller.

### ***Device Activity Log***

Use this option to export device activity logs.

1. Select the log category.
  - All - diagnostic, audit, and patient exam logs.
  - Diagnostic Logs - records all error conditions encountered.
  - Audit Logs - records device activity such as user actions.
  - Patient Exam Logs - records patient scan history.
2. Select calendar icons to specify a starting and ending date range, or select **All History**.
3. Press **Export**. You can either view the log or save the file. To save the file, enter a name for the file and select a location to save it on the scanner controller.

### ***Regular Backups of Image Data***

It is extremely important to back up image data on a regular basis as a matter of routine maintenance. The owner/operator is responsible for performing data backup on the image server.



# **Chapter 5      Data Utilities**

## ***Introduction***

Two data utilities are provided on the SmartScan STUDIO Integration Services DVD:

- FLX Data Utility - scans the patient database for conflicts with patient IDs and patient names. It provides options to move studies and edit patient data to resolve conflicts and export the studies to DEXIS.
- FLX Patient Data Utility - used to make changes to a patient name and/or date of birth. All database conflicts must be resolved using the FLX Data Utility prior to using this utility.

It is highly recommended that both utilities are installed and used on the long-term data storage server (location where SmartScan STUDIO Integration Services resides).

### **NOTE:**

- Only one utility can be used at a time that is accessing the same Image Root. A blocking error will be displayed if more than one user tries to use either utility at the same time on the same Image Root.
- Do not change patient data with either utility if the patient is scheduled for an exam. Wait for the exam to be completed before changing the data. Or, cancel the exam, make the changes, and then re-schedule the exam.
- You must have Administrator permissions to update the Image Root.
- Do not change the SmartScan STUDIO Integration Services configuration while running either utility.
- For sites that are migrating data captured using VisionQ prior to version 1.8.1, use the Vision Data Doctor to update the data to 1.8.1 format before using the FLX data utilities.

## ***FLX Data Utility***

The FLX Data Utility is primarily used to identify and fix conflicts in patient data that result when a site begins to use existing Image Root data with existing DEXIS data. The utility enables you to scan for conflicts in the DICOM patient data from these two sources for the following conditions:

- Patient data is not identical for the same patient
- Two patients have the same patient ID

The utility scans for inconsistencies in patients' first, middle, and last names, prefixes and suffixes, dates of birth, and/or patient IDs, and compiles a list of the conflicts. From the list, you can select the data for review, and edit as appropriate.

The FLX Data Utility also enables you to export patients and studies that were previously captured on a FLX, 17-19 or 3D eXam scanner to the DEXIS database. Additionally, you can display DICOM scans and scouts within the utility that were acquired on the FLX. Raw PAN images are not available for viewing in the utility.

## ***Install and Configure FLX Data Utility***


The FLX Data Utility should have been installed with SmartScan STUDIO Integration Services on the long-term data storage server. If it was not installed, follow steps 1 - 6 to install it. Otherwise, skip to step 7.

For DEXIS sites, if the FLX Data Utility must be used at a workstation other than the long-term data storage server, DEXIS SmartScan STUDIO Integration Services for Server must be loaded on that workstation for the Export to DEXIS Database function to work.

1. Insert SmartScan STUDIO Integration Services DVD in drive.
2. On the AutoPlay pop-up, select **Open folder to view files**.
3. Open Flx Data Utility folder. Double-click **setup**.
4. On the FLX Data Utility window, click **Next**.
5. On the Ready to Install window, click **Install**. The software installs and a progress bar is displayed.
6. When Complete window is displayed, click **Finish**.
7. After the utility has been installed, select the Start menu and right-click **FLX Data Utility** on the menu. Select **Properties**, then select the **Compatibility** tab. Select the **Run this program as an administrator** and click **OK**. The utility will now run with administrator privileges every time it is launched.

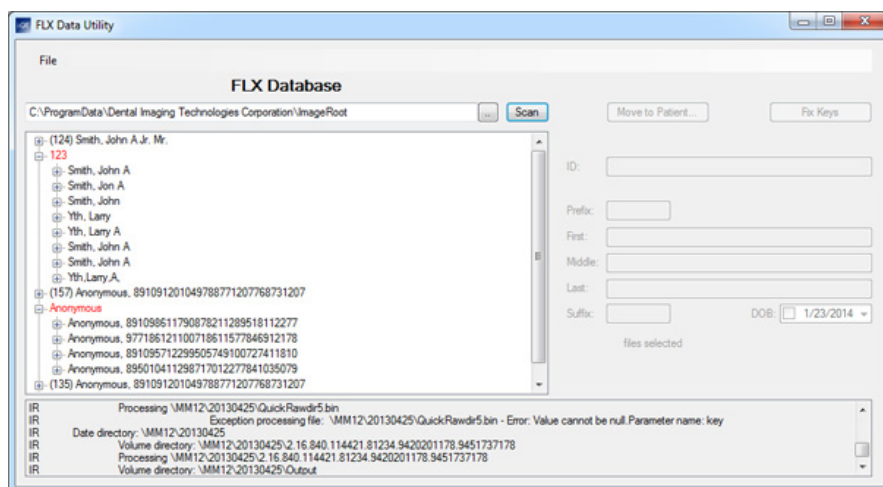
**NOTE:** It is recommended that you pin the utility to the Start menu. The utility can also be launched from All Programs>Dental Imaging Technologies Corporation>Data Utilities.

8. To start the utility, select the Start menu, then **FLX Data Utility**.
9. On initial startup, a message is displayed indicating the image root location is not found. Click **OK**.

10. On the FLX Data Utility window, click  button and browse to the Image Root folder that contains the patient data to be edited. (Typically, this is ProgramData\Dental Imaging Technologies Corporation\ImageRoot.)
11. Select the Image Root and click **OK**.

### Using the FLX Data Utility

1. On the FLX Data Utility window, click **Scan** to scan the selected Image Root for conflicts. A list of patient studies is displayed.



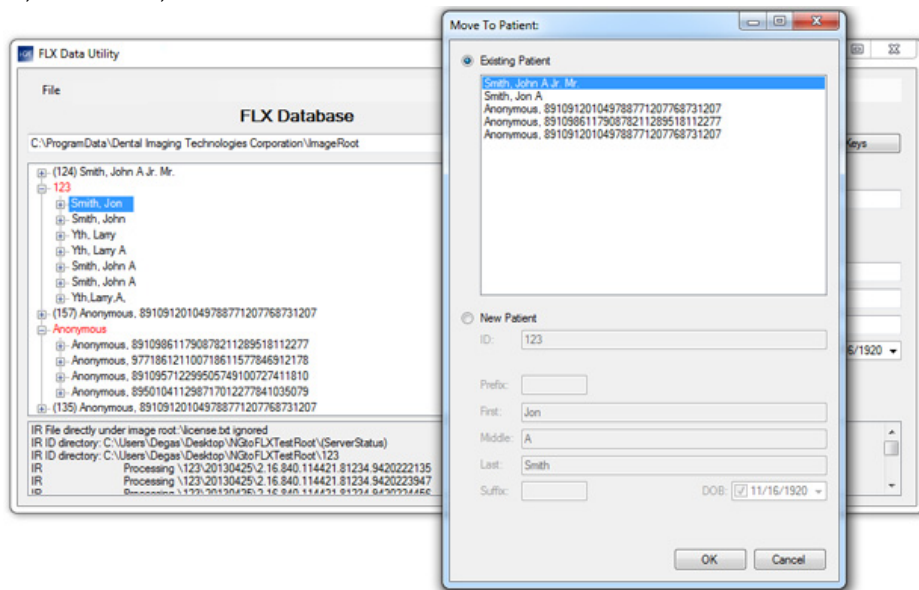
2. Review list for conflicts. Patient IDs that contain conflicts are displayed in red. Look for the following conditions:
  - Patient data not identical for same patient. Identify if multiple patient files that exist under a patient ID refer to the same patient. For example, if the patient first name, last name, middle name or date of birth are not identical but are listed under the same patient ID, determine if the files are for the same patient and edit patient data to be identical.
  - Two patients have the same Patient ID. Identify if all patient files for a patient ID belong to the same patient. If not, move files to the correct patient ID or create a new patient ID and move the files to the new ID.
3. Use procedures below to correct conflicts. It is recommended that you perform all Move to Patient operations first. When you have confirmed that all patient studies

under a single patient ID are for the same patient, you can use the Fix Keys operation to change all these studies to have the same patient data.

4. After changes have been made, click **Scan** to rescan the Image Root. Check that all conflicts have been resolved.
5. Select **File>Exit** to close the utility.

### ***Move a Patient Study to an Existing Patient ID***

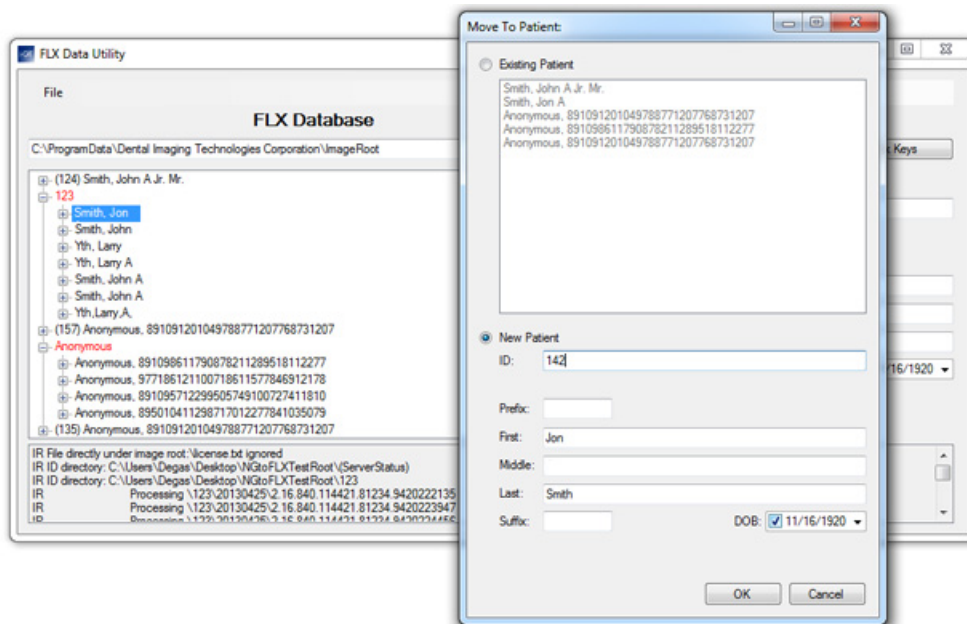
1. Select patient from the FLX Database list, then select **Move to Patient**.
2. On the Move to Patient pop-up (**Existing Patient** radio button selected), a list of all patients is displayed.
3. Select the name of the patient from the list where the patient study is to be moved to. In the example below, the studies for patient “Smith, Jon” will be moved to patient “Smith, John A. Jr, Mr”.



4. Click **OK**. The DICOM files are updated with the requested changes. A progress bar displays and changes are logged at the bottom of the window.
5. When the changes are completed, the FLX Database list is updated with the change.

## Move a Patient Study to a New Patient ID

1. Select patient from the FLX Database list, then select **Move to Patient**.
2. On the Move to Patient pop-up, select the **New Patient** radio button.
3. Complete the fields for patient ID, name and date of birth. In the example below, patient “Smith, Jon” and related studies will be moved to new patient ID “142”.



4. Click **OK**. The DICOM files are updated with the requested changes. A progress bar displays and changes are logged at the bottom of the window.
5. When the changes are completed, the FLX Database list is updated with the change.

## Change a Patient ID (Fix Keys)

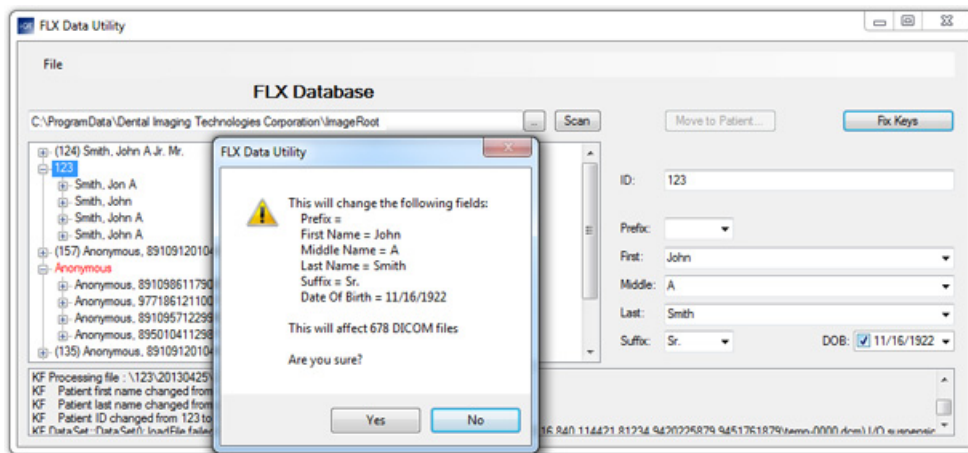
Use this procedure to change all patient data (patient name and date of birth) under a single patient ID to be the same for all studies under that ID.



### CAUTION

Be sure that all studies under the patient ID are for the same patient.

1. Select patient ID from the FLX Database list.
2. Edit the fields for patient ID, name and date of birth as needed. Data entered in these fields will be used to update all patient data and studies under this patient ID. In the example below, all patient data and studies under patient ID “123” will be updated to patient name “John A Smith Sr.” with the date of birth “11/16/1922”.
3. Click **Fix Keys**. A pop-up is displayed showing the data fields that will be changed.

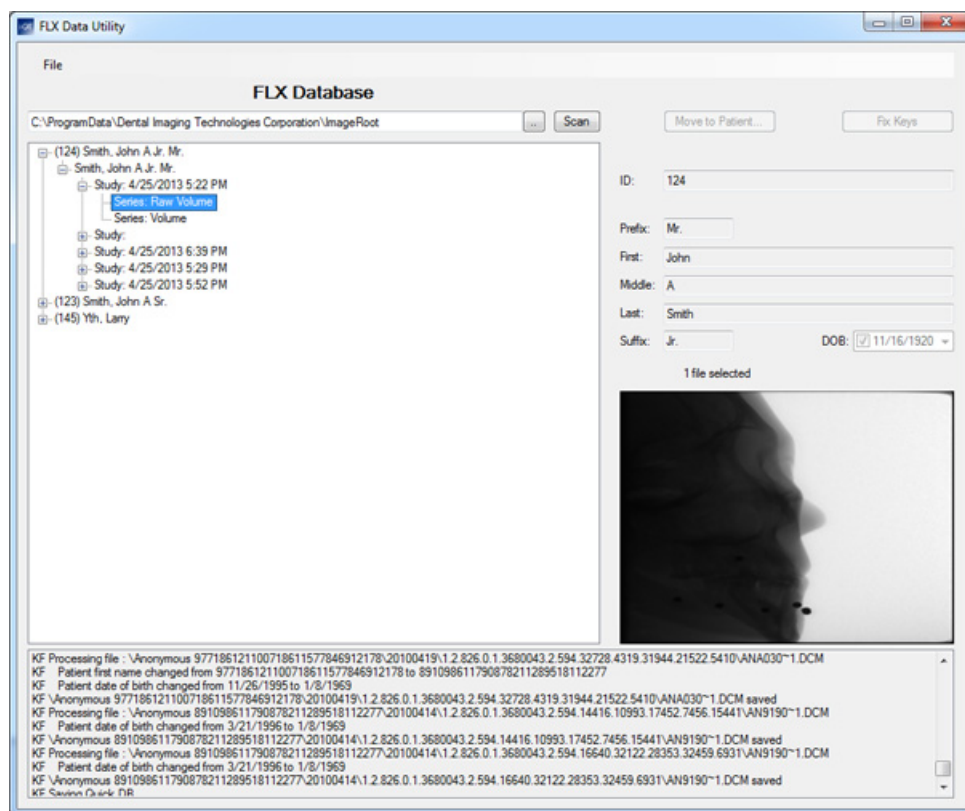


4. Click **Yes** to confirm. The DICOM files are updated with the requested changes. A progress bar displays and changes are logged at the bottom of the window. This may take several minutes depending on the number of files that must be changed.
5. When the changes are completed, the FLX Database list is updated with the change.

## View Study Images For Patient

You can view thumbnail images for a specific patient study that were captured on the i-CAT FLX.

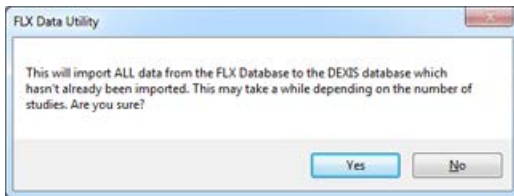
1. Click + next to patient's name to expand the record and display the study entries.
2. Click + next to a study entry to expand the record and display the Series entries.
3. Click on any of the following Series entries to display the image: **Raw Volume** or **Volume**.



## ***Export FLX Database to DEXIS Database***

After conflicts in the FLX database have been resolved, you can export the patient data and studies to the DEXIS database.

1. Select **File>Export to DEXIS DB**. A confirmation pop-up is displayed.



2. Click **Yes** to continue. A progress bar displays and changes are logged at the bottom of the window. All FLX data that was not already exported to the DEXIS database will be exported. The amount of data to be exported will determine how long the operation will take.

## ***FLX Patient Data Utility***

**NOTE:** All database conflicts must be resolved using the FLX Data Utility prior to using this utility.

The FLX Patient Data Utility enables you to edit the following existing patient information in the Image Root:

- Patient name prefix
- First Name
- Middle Name
- Last Name
- Patient name suffix
- Date of Birth

Changes will also be applied to the DEXIS patient database if the site is using DEXIS with SmartScan STUDIO.

Additionally, you can display DICOM scans and scouts within the utility that were acquired on the FLX. Raw PAN images are not available for viewing in the utility.




## ***Install and Configure FLX Patient Data Utility***

**NOTE:** The FLX Patient Data Utility should have been installed with SmartScan STUDIO Integration Services on the long-term data storage server. If it is not installed, follow steps 1 - 6 to install it. Otherwise, skip to step 7.

1. Insert SmartScan STUDIO Integration Services DVD in drive.
2. On the AutoPlay pop-up, select **Open folder to view files**.
3. Open Flx Patient Data Utility folder. Double-click **setup**.
4. On the FLX Patient Data Utility window, click **Next**.
5. On the Ready to Install window, click **Install**. The software installs and a progress bar is displayed.
6. When Complete window is displayed, click **Finish**.
7. After the utility has been installed, select the Start menu and right-click **FLX Patient Data Utility** on the menu. Select **Properties**, then select the **Compatibility** tab. Select the **Run this program as an administrator** and click **OK**. The utility will now run with administrator privileges every time it is launched.

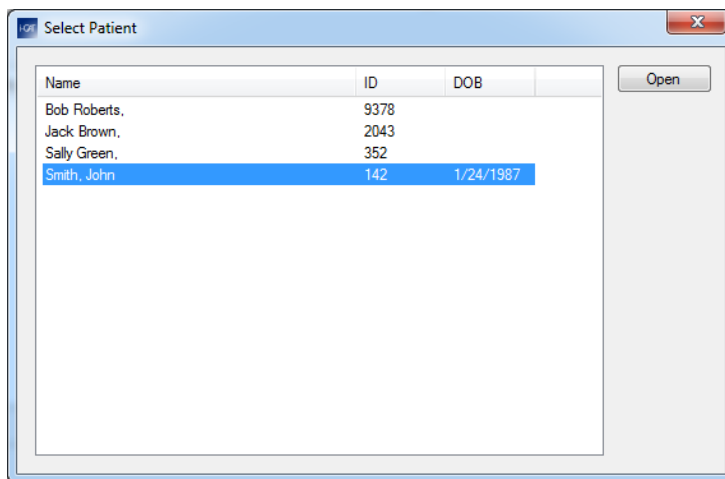
**NOTE:** It is recommended that you pin the utility to the Start menu. The utility can also be launched from All Programs>Dental Imaging Technologies Corporation>Data Utilities.

8. To start the utility, select the Start menu, then **FLX Patient Data Utility**.
9. On initial startup, a message is displayed indicating the image root location is not found. Click **OK**.
10. On the FLX Patient Data Utility window, select **Settings**, then **Configuration**.
11. On Configuration window, click  button and browse to the ImageRoot folder that contains the patient data. (Typically, this is ProgramData\Dental Imaging Technologies Corporation\ImageRoot).
12. Select the ImageRoot and click **OK**.
13. Click **OK** to close the Configuration window.
14. Select **File>Open Patient** to begin using the utility.

## Using the FLX Patient Data Utility

**NOTE:** If there are conflicts in the patient data, you will be prompted to run the FLX Data Utility before continuing.

1. On the Select Patient window, scroll through the list and select the patient entry to edit, then click **Open**.



2. On the main window, edit the patient name fields as needed. Changed fields will display in blue until they are saved. To change the date of birth, click on day, month, or year and enter the correct date, or scroll through the calendar drop-down menu to select the correct date of birth.

**NOTE:** You can view thumbnail images for a specific patient study that were captured on the FLX. Click on an entry under **Studies** with the **Modality** of either **Raw Volume** or **Volume** to display the image.

FLX Patient Data Utility

File Settings

ID: 142

Prefix: First: Middle: Last: Suffix: DOB:

Mr John A Smith 1/24/1987

Studies

Date Time	Modality	FOV	KVP	MA	Voxel Size	# Files
1/24/2014 10:56 AM	Pan	NaN	120.0	5.0	0.51	1
1/24/2014 10:57 AM	Raw Volume	NaN	120.0	5.0	NaN	1

Total files for this patient: 2

PE Quick DB Saved to: C:\ProgramData\Dental Imaging Technologies Corporation\ImageRoot  
 PE Processing file: \142\20140124\2.16.840.114421.1.1.3.1178138551.120.1390579044.409\DX.dcm  
 PE Patient middle name changed from: to A  
 PE \142\20140124\2.16.840.114421.1.1.3.1178138551.120.1390579044.409\DX.dcm saved  
 PE Processing file: \142\20140124\RAW\_2.16.840.114421.1.1.3.1178138551.2656.1390579121.209.dcm  
 PE Patient middle name changed from: to A

Save Done

- When changes are made, click **Save**. A dialog is displayed showing all fields in the DICOM data that will be changed.
- Click **OK** to continue. The DICOM files are updated with the requested changes. A progress bar displays and changes are logged at the bottom of the window.
- Select **File>Open Patient** to select another patient to edit. When finished, click **Done** or **File>Exit** to close the utility.



# **Appendix A**

## **Safety Information**

### **Important Safety Information**

Imaging Sciences designs its products to meet stringent safety standards. However, to maintain the safety of operators and patients, you must operate the equipment correctly and properly and ensure the equipment is properly maintained.

It is essential to follow all safety instructions, warnings, and cautions specified in this manual to ensure the safety of patients and operators. In addition, read and observe all danger and safety labelling on the scanner.



#### **WARNING**

---

Failure to follow instructions below may result in serious bodily injury or death.

---

- The X-ray scanner may be dangerous to the patient and operator if you do not observe and follow operating instructions. Do not operate this scanner unless you have received training to perform a procedure.
- The X-ray scanner may potentially cause detrimental interaction with active implantable medical devices and body worn active medical devices. Contact the manufacturer of such devices for more information.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- No modification of this scanner is allowed except by parties that are authorized by the manufacturer. Use only the software and hardware provided with the scanner.
- Do not remove covers or cables on scanner or operate the scanner with any covers open or removed. High voltage is present in the scanner. Operating the scanner with open or removed covers could expose mechanical operating systems or increase risk of electrical shock that could cause serious or fatal personal injury to the operator or the patient. Only qualified and authorized service personnel should remove covers from the scanner.
- To avoid any potential hazard or danger to operators and patients, contact your authorized Service Representative immediately if you experience any unusual operation, non-recoverable faults, or equipment malfunctions or failures.
- Laser beams can cause optical damage. Instruct the patient to close eyes to avoid looking into the beam.

- Viewing the laser output with certain optical instruments (for example, eye lopes, magnifiers and microscopes) within a distance of 100 mm may pose an eye hazard. Viewing the laser output with certain optical instruments designed for use at a distance (for example, telescopes and Binoculars) may pose an eye hazard.
- Always follow the manufacturer's instructions for proper use and cleaning of the scanner to prevent cross contamination among patients.
- Do not allow liquids in the vicinity of the scanner.
- Closing the gate creates a pinch point. Keep hands and other body parts clear when closing gate.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- In the event of an electrical fire, only use extinguishers that are labelled for that purpose. Using water or other liquids on an electrical fire can lead to fatal or serious personal injury.
- In the event of an electrical fire, to reduce the risk of electrical shock, try to isolate the equipment from the electric source before attempting to extinguish the fire.
- Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with nitrous or oxygen enriched atmospheres.



---

## CAUTION

Failure to follow instructions below may result in minor or moderate bodily injury or damage to the device.

---

- If the optional deadman handswitch is installed on the scanner, press and hold handswitch before pressing the **Scan** button, and continue to hold handswitch down for the duration of the exposure (**X-ray** light on). Early release of the handswitch stops the exposure and the **Fault** light turns on. The patient will have to be re-scanned.
- If the scanner or the scanner controller is powered off, at scanner power up or scanner controller boot up, when the first scan is initiated (scout or full scan), the i-CAT FLX performs a reset procedure that may delay the start of first scan.

## ***Electrical Hazards***

Installation and scanner wiring must meet all requirements of local governing authorities. Please check your local authorities and local codes to determine best practices for a safe installation.

Do not place any liquid or food on any part of the scanner controller or other modules of the scanner.

Observe all fire regulations. Fire extinguishers should be provided for both electrical and non-electrical fires. All operators should be fully trained in the use of fire extinguishers and other fire-fighting equipment and in local fire procedures.

## ***Explosion Hazard***

Do not use the scanner in the presence of a flammable anaesthetic mixture with air or with nitrous or oxygen enriched atmospheres, explosive gases or vapors, including anaesthetic gases. Use of this scanner in an environment for which it is not designed can lead to fire or explosion.

If hazardous substances are detected while the scanner is turned on, do not attempt to turn off the scanner. Evacuate the area and then remove the hazards before turning off the scanner.

## ***Mechanical Hazards***

Carefully observe the patient during the scanning procedure to ensure that when the scanner gantry moves, the patient does not collide with the gantry or other equipment. Ensure that the patient does not grab or hold any part of the scanner or nearby equipment.

### ***Collision System***

The gantry motor is programmed to operate at a rotational force of  $\leq 15$  lbf (66.7N). Interference or incidental contact with the gantry during rotation, which results in an interruption in gantry motion, will be detected and trigger a scanner stall event. This will result in a scanner fault condition which will cause the following events to occur:

- Stepper motor power is removed
- X-Ray operations cease
- Scanner Fault Light illuminates
- X-Ray audio and visual indicators de-energize

If a collision occurs, the message **A scanner stall was detected** is displayed on the scanner controller. The dialog box instructs the operator to clear the patient environment. The operator should lower the chin support and remove the patient or other obstacles. When completed, the operator should press OK on the dialog box. The scanner recovers automatically and will initialize for normal use.

### ***Tube Head Leakage***

The tube head contains mineral insulating oil. Such oils are potentially harmful in case of ingestion or contact with skin or eyes. In case of a defect or fault, an oil leak can occur. Avoid direct contact with the oil and do not inhale its vapors. Call your authorized Service Representative to repair the problem.

In case of minor leakage, the oil can be wiped away with a dry cloth, wearing protective gloves. If contact with skin or eyes occurs, flush with plenty of water.

### ***Laser Beam Hazards***

The scanner gantry has laser markers to assist you in positioning patients. If you are using the laser markers while a patient is in the chair, warn the patient that the laser beam could be harmful. Advise the patient that laser beams can cause optical damage. Instruct the patient not to stare at the laser beam and to avoid looking into the beam.

### ***Radiation Safety***

The scanner produces X-rays useful for producing dental images. X-rays are electromagnetic radiation with wavelengths in the 10 to 0.01 nanometer range. X-rays have the property of penetrating thicknesses of material, being absorbed by dense material but passing through less dense material with lower attenuation. X-rays are also considered ionizing radiation which can remove electrons from atoms or molecules. Exposure to any ionizing radiation increases the risk of serious illness. X-rays can also result in radiation burns if skin is exposed to excessive amounts.

The scanner provides a high degree of protection from unnecessary radiation. However, no practical design can provide complete protection nor prevent operators from exposing themselves or others to unnecessary radiation. It is important to restrict use and follow all applicable government radiation protection regulations.

Pregnant women should not be exposed to X-rays unless necessary. Proper safety precautions should be taken to minimize dose to the fetus.



## ***Radiation Protection Measures***

Use the following measures to protect yourself and the patient from unintended exposure to radiation. Anyone who is near the patient during test procedures must observe the following precautions:

- Maintain adequate distance from exposed radiation source.
- Keep exposure times to a minimum.
- Use protective clothing (lead apron, etc.) for all patients.
- Wear a PEN dosimeter and/or film badge.
- The physician is responsible for protecting the patient from unnecessary radiation.

## ***Safety Devices***

### ***Emergency Stops***

In the event of an emergency, the operator and/or patient should use the Emergency Stop buttons to turn off the power to all moving parts in order for the patient to be safely removed from the scanner. Emergency Stop buttons are located on the operator control box and the Patient Emergency Stop control. An emergency could arise if any moving component collides with any parts of the scanner or items in the environment, or if the patient moves or needs immediate assistance for some reason.

If the Emergency Stop button is pressed, the message **The Emergency Stop button was activated** is displayed in a dialog box. The dialog box instructs the operator to clear the patient environment. The operator should lower the chin support and remove the patient or other obstacles. To reset an Emergency Stop button, pull and turn button clockwise. When completed, the operator should press OK on the dialog box. The scanner recovers automatically and will initialize for normal use.

### ***Warning System***

The scanner is equipped with provisions for warning lights and/or audible alarms when X-ray power is energized. An externally powered warning system can be connected to the cable provided which is capable of 250 volts, 50/60 hertz, and 2.5 amps. When X-ray power is energized the warning system is also energized.

### Interlock System

The scanner is equipped with provisions for a low voltage 12 volts DC interlock circuit which, when opened, will turn off X-ray power. The interlock circuit can be used for a door interlock switch, a deadman handswitch, or both. Use of the interlock circuit is optional based on site requirements.

Interlock Uses	Requirements
Door Interlock	Requires site-supplied interlock switch and interlock cable supplied with scanner.
Deadman Handswitch	Optional handswitch and cable that can be purchased with the scanner.
Door Interlock and Deadman Handswitch	Above requirements and a site-supplied junction box.

### Site Layout

The scanner controller and touch screen electrically connected to the scanner conforms to IEC 60950-1 and 60601-1.

Normally, the scanner controller and touch screen are placed outside the patient environment, but may be placed inside the patient environment if required by the customer site. The operator control box must be placed outside of patient environment. All other accessories are suitable for use in the patient environment. Room layouts must provide a means for audio and visual communication between the operator and patient. The patient emergency stop control, which can stop the operation of the X-ray device, must be within reach of the patient when scanning occurs.

IEC 60601-1 defines the “patient environment” as “any volume in which intentional or unintentional contact can occur between a patient and parts of the ME Equipment or ME System or between a patient and other persons touching parts of the ME Equipment or ME System.”

### Cabling Requirements

Scanner cabling connections must be installed away from walkways and doorways. It is recommended to run cabling along wall perimeters. If there is a chance of mechanical damage due to the cable location, then the use of conduit or other means of protection should be considered.

**NOTE:**

1. Connection of the i-CAT FLX to the customer network/data coupling that includes other equipment could result in previously unidentified risks to patients, operators, or third parties.
2. The customer should identify, analyze, evaluate and control these risks.
3. Subsequent changes to the network/data coupling could introduce new risks and require additional analysis.
4. Changes to the network/data coupling include:
  - changes in network/data coupling configuration.
  - connection of additional items to the network/data coupling.
  - disconnecting items from the network/data coupling.
  - update of equipment connected to the network/data coupling.
  - upgrade of equipment connected to the network/data coupling.



# **Appendix B**

## **Product Information**

### **Essential Performance**

The essential performance of the i-CAT is defined below:

- The ability of the i-CAT system (including scanner controller, positioning system, and imaging software) to capture 2D and 3D X-ray scans and reconstruct images suitable for recognition of normal anatomical structures, dental pathologies, and abnormal conditions, where inadequate images may result in misdiagnosis, subjecting the patient to incorrect or unnecessary dental procedures that would present an unacceptable risk to the patient.
- The ability of i-CAT models to function reliably over the specified environmental and input voltage requirements, provide electrical isolation of the patient from mains voltages, have low leakage current, and control the motion system where inability to meet these requirements can result in electrical shock resulting in injury or death, injury due to collision caused by loss of motion control, or require an additional re-scan because of equipment malfunction that will increase the risk of serious illness and present an unacceptable risk to the patient.
- The ability of i-CAT models to provide mechanical safety and stability to provide optimum and consistent images, avoid any injury to the patient, and prevent the need for a re-scan that would present an unacceptable risk to the patient.
- The ability of i-CAT models to meet electromagnetic compatibility requirements for emissions and susceptibility where inability to meet EMC performance requirements could result in possible degraded performance, inaccurate or distorted images, or interference with other medical equipment resulting in incorrect or unnecessary dental procedures or malfunction of other electrical equipment that would present an unacceptable risk to the patient.
- The ability of i-CAT models to meet radiation performance and protection requirements where inability to meet these requirements can result in increased dose to patient or inadequate images that result in misdiagnosis, subjecting the patient to incorrect or unnecessary dental procedures that would present an unacceptable risk to the patient.

### **User Proficiency**

The i-CAT is designed to be operated by healthcare professionals who are educated and competent in the techniques described in the accompanying documentation. Specific educational requirements are determined by state and/or national regulatory agencies. Operators are strongly

urged to comply with the current recommendations of the International Commission on Radiological Protection and, in the United States, the US National Council for Radiological Protection.

It is strongly recommended that all operators complete i-CAT training. Contact Customer Service to schedule a training session. Basic computer skills and understanding of the Microsoft Windows® operating system are required.

The operator must be able to read and understand the language in which the accompanying documentation is written.

Visual impairment is permissible as long as the operator can resolve the necessary details of the accompanying documentation, user interface and image data. Use of corrective measures such as glasses or contact lenses is permissible. In addition, the user should be able to discern visual indications such as LEDs that light up while X-rays are being emitted, system on/off or when the system has a fault.

Audio impairment is permissible as long as the operator can discern audio indications emitted by the scanner or other associated equipment, such as the audible alarms that sounds while X-rays are being emitted, or, in the case of deafness, as long as such audio indications are supplemented by corresponding visual indications. Use of corrective measures such as hearing aids is permitted.

General physical impairments involving the arms, legs and/or motor skills are permissible as long as the operator can perform all of the tasks required for proper operation of the scanner as described in the accompanying documentation.

## **Service**

The expected service life of the scanner is ten years. Incorrect operation or failure to maintain the scanner in accordance with the maintenance schedule relieves the manufacturer or his agent from all the responsibilities for subsequent non-compliance, damage, injury, defect and/or other malfunction. It is strongly recommended that only authorized Service Representatives maintain and service the scanner. Circuit diagrams, parts lists, and other information are available on request for parts that are designated as repairable by service personnel.

Installation of the scanner must be performed by authorized Service Representatives following instructions provided in the Installation Manual shipped with the scanner. It is the responsibility of the owner to ensure that existing legal regulations regarding installation of the scanner with respect to the building are observed.

Modifications and additions to the scanner (including replacement of power cords and exposure switches) must be carried out only by personnel or third parties that are expressly authorized by Imaging Sciences International (ISI), and must comply with the applicable legal requirements as well as with the generally accepted technical regulations.

## Technical Specifications

### X-ray Source

Tube Voltage:	120 kVp(eff)
Tube Current:	3-7 mA
Voltage Wave Shape:	Constant Potential
Focal Spot:	0.5
Duty Cycle:	3%

**Source to Sensor distance:** 71.4 cm

**Source to Patient distance:** 49.53 cm (center of rotation)

**NOTE:** The patient must be properly positioned in the Head Support for each patient for all applications in order to have the focal spot to skin distance as large as possible.

**Minimum Focal Spot to Skin Distance:** 43 cm

**Minimum Filtration (at 120 kVp(eff)) (mm of aluminum equivalent):** 10 mm or greater

**Maximum Rated Continuous Tube Operation:** 130 kVp @ 0.5 mA

**Maximum Rated Pulsed Tube Operation:** 130 kVp @ 1mA

**NOTE:** Leakage technique factors are measured at the maximum specified energy.

**Maximum Deviation:** kV: +/- 5 kV

**mA:** + 10%

**Timer:** +/- 0.01 seconds or 5%, whichever is greater

**Maximum Excursion:** 15 kV at 120 kV

**X-ray Beam Size:** Rectangular cone 23.8 cm width x 5 cm to 19.2 cm height

**PAN option:** Rectangular cone 1 cm width x 10 cm height

(Automatically collimated not to exceed image detector readable area)

**Image Detector:** Amorphous Silicon Flat Panel (readable area), 24.2 cm width x 19.3 cm height

**Sensor Front Panel Attenuation Value:** Less than 1 mm of aluminum equivalent (information for reference only)

**Gray Scale:** 16 bit

**Image Acquisition:** Single 360 degree rotation (maximum)

**Stopping Distance and Angle:** Hard stop is at -45° and 470° (reference is the gantry at the home position being 0°). Platform travel is 69 mm.

# Power Requirements

The scanner uses facility power and requires a dedicated line. A surge protector is recommended. The scanner is suitable for continuous connection to a power supply in stand-by mode.

**Line Voltage:** 100VAC, 115VAC, 200VAC or 230VAC (Factory Set)

**Line Voltage Regulation requirement:** + 10%

**Line Current:** 15 Amps (100V), 10 Amps (115V), 7.5 Amps (200V) or 5 Amps (230V)

**Line Frequency:** 50 Hz / 60 Hz

**Phase:** Single

**Main Circuit Breaker:** 15 Amps (100V), 10 Amps (115V), 7.5 Amps (200V), or 5 Amps (230V)

**Nominal Electrical Power:** 251W for pulsed operation at 120kV, 5mA and scan time of 8.9s with a duty cycle of 42%. The highest output power during this time is 600W.

**Nominal Electrical Input Power to Supply:** Volume Scan = 300W (120kV, 5mA); PAN Scan (Large) = 625W (94kV, 5mA). Scan Time has no effect on electrical power output.

**Scanner Controller:** Requires a dedicated line and a surge protector is recommended.

## Apparent Resistance of Supply Mains

For the purpose of obtaining the apparent resistance of supply mains, resistance is determined according to the following formula:

$$R = \frac{U0 - U1}{I1}$$

**Where:**

U0 is the no-load Mains Voltage

U1 is the Mains Voltage under load

I1 is the Mains Current under load

Circuit Breaker Assembly	U0	U1	I1	Apparent Resistance
100VAC	100.3VAC	96.8VAC	5.22A	0.67 ohms
115VAC	115.4VAC	113.0VAC	4.36A	0.55 ohms
200VAC	200.4VAC	194.1VAC	2.62A	2.40 ohms
230VAC	230.8VAC	223.0VAC	2.31A	3.37 ohms



## ***Weight***

**Total Weight:** 510 lbs. (231.3 kg)

**Tube Head Pod:** 35.5 lbs. (16.1 kg)

**Receptor Pod:** 57 lbs. (25.9 kg)

**X-Ray Power Supply:** 9 lbs. (4.1 kg)

## ***Patient Support Chair***

**Overall dimensions:** 72.4 cm x 61 cm x 109.2 cm

**Weight:** 125 lbs (56.7 kg)

**Seat height adjustment:** 35.65 cm to 73.7 cm

**Maximum patient weight:** 400 lbs (181 kg)

Complies with IEC 60601-2-32:1994

## ***Environmental Specifications***

### ***Operating***

50 to 95 degrees Fahrenheit (10 to 35 degrees Celsius)

10% to 90% Relative Humidity, non-condensing

70 to 106 kPa Air Pressure

### ***Transportation and Storage***








-4 to 158 degrees Fahrenheit (-20 to 70 degrees Celsius)

10% to 90% Relative Humidity, non-condensing

70 to 106 kPa Air Pressure

Labels

The following labels are attached to the scanner or scanner components.

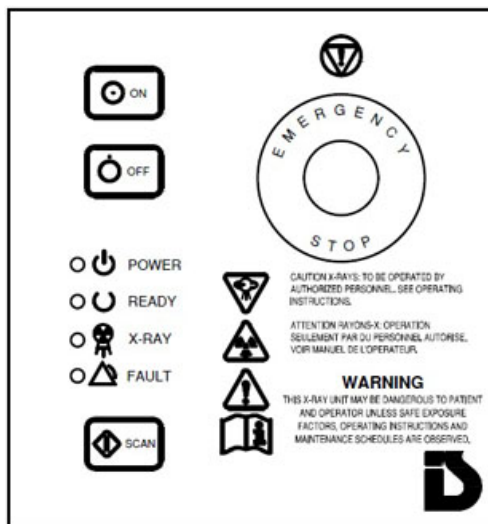
Label Definition and Location	Symbol Definition
<p><b>Patient Emergency Stop Panel Label</b></p> <p>Location: Can either be hung from the chair support mechanism or held in the patient's hand.</p>  A grey rectangular panel with a large yellow circular button in the center. The word "EMERGENCY" is written in a semi-circle above the button and "STOP" is written below it. Below the button is a small yellow circle with a black 'V' inside, and at the bottom is a blue stylized 'D' logo.	 A black circle with a white exclamation mark inside. <p>EMERGENCY STOP</p>
<p><b>Indicator Panel Label</b></p> <p>Location: Front Overhead</p>  A horizontal bar with four colored sections: green, green, yellow, and red. Each section has a symbol and text. From left to right: a power symbol and "POWER", a circle with a dot and "READY", a radiation symbol and "X-RAY ON", and a triangle with an exclamation mark and "FAULT". Above each section is a small indicator light: green, green, orange, and red.	 A black power symbol (a circle with a vertical line through the top). <p>POWER</p>  A black circle with a dot in the center. <p>READY</p>  A black radiation symbol (a circle with three curved lines and a central dot). <p>X-RAY ON</p>  A black triangle with an exclamation mark inside. <p>FAULT</p>

**CAUTION X-RAYS: TO BE OPERATED BY AUTHORIZED PERSONNEL. SEE OPERATING INSTRUCTIONS.**

**WARNING**

**THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS, OPERATING INSTRUCTIONS AND MAINTENANCE SCHEDULES ARE OBSERVED.**

Location: Operator Control Box



Turns Unit On



Turns Unit Off



Starts the Scan



Power



Ready



X-Ray



Fault



Emergency Stop



X-Ray Radiation











Ionizing Radiation












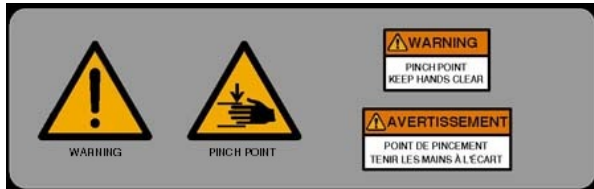


Warning



Operating Instructions

<p><b>CAUTION: LASER RADIATION</b> <b>DO NOT STARE INTO BEAM</b> <b>&lt;1mW 635nm CLASS II LASER PRODUCT</b> Location: X-Ray Source</p> 	<div> Warning</div> <div> Laser</div>
<p><b>CAUTION: LASER RADIATION</b> <b>DO NOT STARE INTO BEAM</b> <b>&lt;1mW 670nm CLASS II LASER PRODUCT</b> Location: Gantry</p> 	<div> Warning</div> <div> Laser</div>
<p><b>PANEL ONLY TO BE REMOVED BY ISI TRAINED SERVICE PERSONNEL</b> Location: Beam Limiter Panel</p> 	<div> Warning</div>

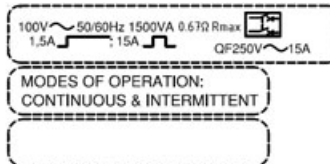
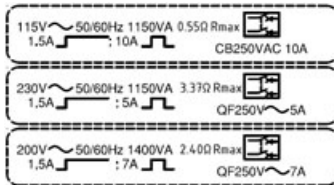
<div><div><b>Patient Alignment Panel</b></div><div>Location: X-Ray Source Assembly</div><div></div></div>	<div><div> Laser</div><div> Seat Height Adjustment</div></div>
<div><div><b>Chair Warning Label</b></div><div><b>MAXIMUM LIFTING CAPACITY</b> <b>≤ 182 KG (≤400 LBS)</b></div><div>Location: Chair Assembly</div><div></div></div>	<div><div> Warning</div><div> Maximum Lifting Capacity</div></div>

<p><b>Chair Installation Label</b>  <b>WARNING PINCH POINT</b>  <b>KEEP HANDS CLEAR</b>  <b>Seat Weighs 6.8 KG (15 LBS)</b></p> <p>Location: Seat Assembly</p>  <p>The label is rectangular with a black border. It features a large black rectangular area at the top. Below this, on the left, is a yellow triangle with a black exclamation mark, labeled 'WARNING' and 'PINCH POINT KEEP HANDS CLEAR'. In the center is a yellow triangle with a black hand icon being pinched, labeled 'WARNING' and 'PINCH POINT KEEP HANDS CLEAR'. On the right is a yellow triangle with a black exclamation mark, labeled 'AVERTISSEMENT' and 'POINT DE PINCEMENT TENIR LES MAINS A L'Ecart'. At the bottom left is a small icon of a seat with the text '6.8 KG (15 LBS)' and 'SEAT WEIGHT'.</p>	 <p>Pinch Point</p>  <p>Seat Weight</p>
<p><b>Gate Label</b>  <b>WARNING PINCH POINT</b>  <b>KEEP HANDS CLEAR</b></p> <p>Location: Chair Gate</p>  <p>The label is rectangular with a black border. It features two yellow triangles with black exclamation marks, labeled 'WARNING' and 'PINCH POINT'. To the right of these are two yellow triangles with black hand icons being pinched, labeled 'WARNING' and 'PINCH POINT'. On the far right are two yellow triangles with black exclamation marks, labeled 'AVERTISSEMENT' and 'POINT DE PINCEMENT TENIR LES MAINS A L'Ecart'.</p>	 <p>Warning</p>  <p>Pinch Point</p>

## Rear Overhead Label

### Modes of Operation: Continuous & Intermittent

Location: Rear Overhead



Warning



Electrical Hazard



Complies With  
Type-B Body



Non-Ionizing  
Radiation



Not For General  
Waste



1520

Chair Cable



1518

Control Box Cable



1525

Interlock Cable



1527

Warning Cable



Network Cable



Breaker Switch  
On/Off



12VDC  
20mA











Output for Interlock



AC In



Continuous : Intermittent

<div><div>Fuse Label</div><div>Location: Rear Overhead</div><div><div><div><div><div><div>F250mA, 250V</div><div></div></div><div>DOOR INTERLOCK</div></div><div><div><div>F250mA, 250V</div><div></div></div><div>DOOR INTERLOCK</div></div><div><div><div>T2-1/2A, 250V</div><div></div></div><div>X-RAY ON LAMP</div></div><div><div><div>T10A, 250V</div><div></div></div><div>X-RAY SOURCE ASSY</div></div></div></div></div><div><div> Door Interlock</div><div><div> X-Ray On Lamp</div><div> X-Ray Supply</div><div> Fuse</div></div></div></div>	
<div><div>X-Ray Power Supply Label</div><div>MODES OF OPERATION: CONTINUOUS &amp; INTERMITTENT COMPLIES WITH IEC 60601-2-7 AND IEC 60601-2-28</div><div>Location: X-Ray Power Supply</div><div><div><div>X-RAY POWER SUPPLY</div><div>115V ~ 50/60Hz, 10A</div><div>MODES OF OPERATION: CONTINUOUS &amp; INTERMITTENT</div><div></div><div>COMPLIES WITH IEC 60601-2-7 AND IEC 60601-2-28</div></div></div></div>	<div><div></div><div>Continuous : Intermittent</div></div>



### Capacitor Warning Label

**Capacitor Has >300VDC**

**Wait 5 minutes for capacitor discharge before handling.**

Location: X-Ray Power Supply



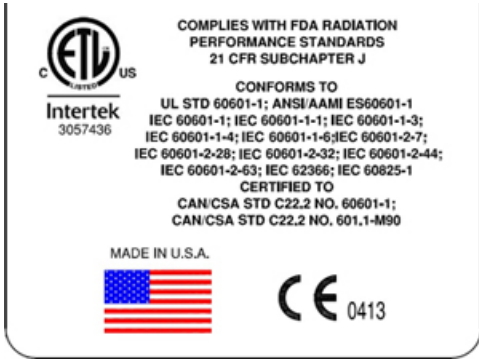
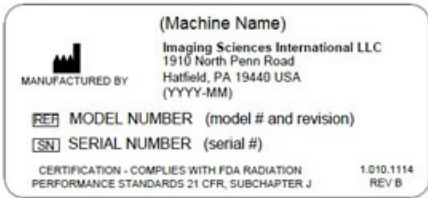
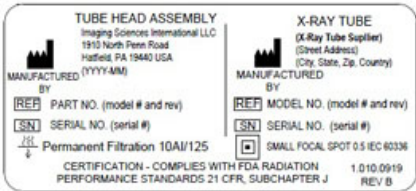





Warning

### Capacitor Caution Label

**DO NOT USE GROUNDED TEST EQUIPMENT ON THIS UNIT**

Location: X-Ray Power Supply



<p><b>CE/ETL Label</b></p> <p>Location: Leg</p> <div data-bbox="262 325 736 686"><p>The CE/ETL label is rectangular with a rounded bottom. It features the ETL logo (a circle with 'ETL' inside) and 'Intertek 3057436' on the left. The text in the center reads: 'COMPLIES WITH FDA RADIATION PERFORMANCE STANDARDS 21 CFR SUBCHAPTER J', 'CONFORMS TO', 'UL STD 60601-1; ANSI/AAMI ES60601-1', 'IEC 60601-1-1; IEC 60601-1-1-1; IEC 60601-1-3;', 'IEC 60601-1-4; IEC 60601-1-6; IEC 60601-2-7;', 'IEC 60601-2-28; IEC 60601-2-32; IEC 60601-2-44;', 'IEC 60601-2-63; IEC 62366; IEC 60625-1', 'CERTIFIED TO', 'CAN/CSA STD C22.2 NO. 60601-1;', 'CAN/CSA STD C22.2 NO. 601.1-M90'. At the bottom, it says 'MADE IN U.S.A.' with a US flag and the CE mark with '0413'.</p></div>	
<p><b>Serial Labels</b></p> <p>Location: Leg</p> <div data-bbox="308 861 731 1059"><p>The label is rectangular with a rounded top. It features a factory icon and the text: '(Machine Name)', 'Imaging Sciences International LLC', '1910 North Penn Road', 'Hatfield, PA 19440 USA', '(YYYY-MM)'. Below this, it says 'MANUFACTURED BY' followed by a box labeled 'REF' and 'MODEL NUMBER (model # and revision)', and another box labeled 'SN' and 'SERIAL NUMBER (serial #)'. At the bottom, it reads 'CERTIFICATION - COMPLIES WITH FDA RADIATION PERFORMANCE STANDARDS 21 CFR, SUBCHAPTER J' and '1.010.1114 REV B'.</p></div> <p>Location: Tube Head Assembly and Packing Crate</p> <div data-bbox="314 1149 725 1340"><p>The label is rectangular with a rounded top. It is divided into two sections. The left section is for the 'TUBE HEAD ASSEMBLY' by 'Imaging Sciences International LLC' and includes 'MANUFACTURED BY (YYYY-MM)', 'REF PART NO. (model # and rev)', 'SN SERIAL NO. (serial #)', and 'Permanent Filtration 10Al/125'. The right section is for the 'X-RAY TUBE' by '(X-Ray Tube Supplier) (Street Address) (City, State, Zip, Country)' and includes 'MANUFACTURED BY', 'REF MODEL NO. (model # and rev)', 'SN SERIAL NO. (serial #)', and 'SMALL FOCAL SPOT 0.5 IEC 60336'. At the bottom, it reads 'CERTIFICATION - COMPLIES WITH FDA RADIATION PERFORMANCE STANDARDS 21 CFR, SUBCHAPTER J' and '1.010.0919 REV B'.</p></div>	<div data-bbox="913 778 982 855"></div> <p>Manufactured By</p> <div data-bbox="913 861 982 893"></div> <p>Model No.</p> <div data-bbox="913 900 982 932"></div> <p>Serial No.</p> <div data-bbox="913 938 982 995"></div> <p>Filtration</p> <div data-bbox="913 1002 982 1066"></div> <p>Focal Spot</p>

**Do Not Use with i-CAT SCAN  
Only Use with i-PAN SCAN**

Location: PAN Head Holder

**Push to Release Label**

Location: PAN Head Holder



## ***Proper Disposal of Electronic Equipment***

**CAUTION**

Do not dispose of any parts of this product with industrial or domestic waste. Incorrect disposal of any of these materials may lead to serious environmental pollution.

### ***Product Disposal***

The X-ray source assembly, image sensor and all electronic circuits should be regarded as non environmental friendly waste product. The scanner does not generate, or require the use of, any materials that require special disposal instructions as part of regular operation.

The manufacturer of this product is concerned to help protect the natural environment, and to help ensure continued safe and effective use of this product, through proper support, maintenance and training. Therefore products are designed and manufactured to comply with

relevant guidelines for environmental protection. As long as the product is properly operated and maintained, it presents no environmental risks.

However, the product may contain material, which could be harmful to the environment if disposed of incorrectly. Use of such material is essential to performing the functions of the product, and to meeting statutory and other requirements.

**NOTE:** The following information regarding proper disposal is valid in the European Union. For locations outside of the European Union, please contact your local authorities or dealer and ask for the correct method of disposal.

For proper treatment, recovery, and recycling, please take these products to designated collection points where they will be accepted on a free-of-charge basis. Alternatively, in some countries, you may be able to return your products to your local retailer upon the purchase of an equivalent new product.

Disposing of this product correctly will help to save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling.

Please contact your local authority for further details of your nearest designated collection point. Penalties may be applicable for incorrect disposal of this waste in accordance with national legislation.

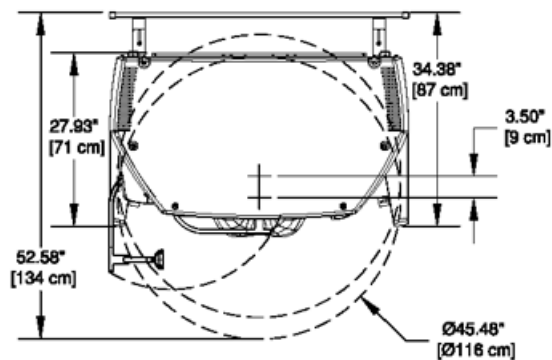
### ***Passing the Product on to Another User***

If this product passes to another user, it must be in its complete state, including all product support documentation. Make the new user aware of the support services that the manufacturer provides for installing, commissioning and maintaining the product.

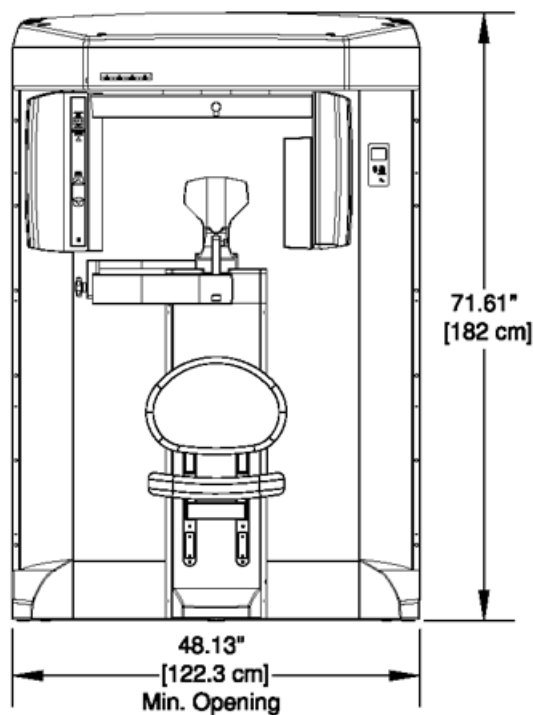
Before passing on the product or taking it out of service, all patient data must be backed up (elsewhere if necessary) and unrecoverable data be deleted on the product. It must be remembered by all existing users that passing on medical electrical products to new users may create serious technical, medical and legal (e.g. privacy) risks. Such risks can arise even if the product is given away.

Existing users are strongly advised to seek advice from their local dealer representative before committing themselves to passing on any product. Once the product has been passed on to a new user, a previous user may still receive important safety-related information, such as bulletins and field change orders. In many jurisdictions, there is a clear duty on the previous user to communicate such safety-related information to new users. Previous users who are not able or prepared to do this should inform the manufacturer about the new user, so that safety-related information can be provided to the new user.

## Scanner Dimensions



TOP VIEW



FRONT VIEW

## ***Preventive Maintenance Schedule - for Owner / User***

**Daily:** Routine Dusting - all surfaces

**Monthly:** Clean all surfaces and check for failed/faulty indicator lights.

**Yearly:** Check for satisfactory image quality.

**NOTE:** It is the responsibility of the user to insure that the equipment is maintained in compliance with the manufacturer's recommended maintenance schedule. The manufacturer and the assembler / installer are relieved from responsibility in those cases where non-compliance with the standard results from the user's failure to have the manufacturer's recommended maintenance performed.

The actual maintenance inspection and consequent service must be accomplished either by an authorized dealer or by a competent serviceman of the user's choice who has adequate training in those aspects of the Performance Standards of the Radiation Control for Health and Safety Act of 1968 that are applicable to this equipment.

Neither the inspection nor service is part of the equipment warranty. Please arrange for preventive maintenance with the Dealer's Service Department.

## ***Cleaning***

Routinely clean and disinfect all items which come in contact with the patient. Use Opti-Cide<sup>3®</sup> Solution and/or Wipes from Biotrol International, or equivalent cleaner and disinfectant. Saturate with Opti-Cide<sup>3®</sup> and allow surface to remain wet for three minutes at room temperature (69°F / 20°C), and then wipe dry using a clean paper or cloth towel. See Opti-Cide<sup>3®</sup> label for full instructions. The following items may come in physical contact with the patient during a scan:

- Patient Emergency Stop
- Head Support
- Chin Cup/Chin Rest
- PAN Head Holder
- Booster Seat/Foot Stool
- Bite Tips

Clean the equipment surfaces frequently, especially if corroding chemicals are present. Unless otherwise instructed, use a cloth moistened with warm water and mild soap and wipe all surfaces to remove surface dirt and marks. Do not use strong cleaners and solvents as these may damage the finish. It is recommended to power off equipment before cleaning. Be careful to avoid liquid leaking inside the gantry.

## ***Planned Maintenance - 12 Month Schedule***

The Planned Maintenance philosophy for this scanner is based upon the assumption that a periodic inspection of the equipment, along with periodic cleaning and calibration, will maintain image quality.

The scanner requires normal periodic inspection and maintenance. Scheduled periodic inspections are necessary to detect problems which can result from excessive wear, loose items, chafing wires, and mis-adjusted parts from continual scanner use.

In addition to mechanical inspection and calibration, a series of image performance tests are to be conducted. These tests verify that the scanner meets or exceeds operational specifications and that it will provide continued excellent image quality.

Planned maintenance is to be performed annually by a factory-trained Service Representative.

### ***Planned Maintenance Checklist***

Perform Calibrations	
	Panel Calibration
	Shutter Calibration
	Geometric Calibration
	Check Detector Pivot (displayed during GeoCal, both Portrait and Landscape)
Perform QA Tests	
	QA Line Pair
	QA Material
	QA Air Water
	PAN Phantom Test
	Radiation Output Test (performed by qualified personnel, per local requirements)
Perform Chair Calibration	
	Check Patient Chair Center Alignment
	Check Patient Chair Level

Check Laser Alignments	
	Check Centerline Alignment
	Check Crosshair Laser
Inspect Tube Housing Components	
	Certification Label
	Warning and Indicators
	Oil Leaks
	Physical Damage
	Scanner Mounting Stability
Inspect Beam Limiting Device	
	Physical Damage
	Certification Label
Check/Inspect X-Ray Controller	
	Visual Warning Indicator
	Audible Exposure Signal
	Certification Label

## ***Replaceable Parts***

There are no equipment parts designated as repairable in the field by the owner/user of the equipment, including fuses. Contact your Service Representative if repairs are needed.









## Supplemental Components

	<p><b>Patient E-stop</b>  <b>Part # 1304-0</b>  <b>Quantity: 1</b></p>		<p><b>Carbon Fiber Head Rest</b>  <b>Part # 27-0</b>  <b>Quantity: 1</b></p>
	<p><b>Glide</b>  <b>Part # 910-24</b>  <b>Quantity: 4</b></p>	 	<p><b>Head Restraint Band</b>  <b>Part # 27-1</b>  <b>Quantity: 50</b></p>
	<p><b>Tool Kit</b>  <b>Part # 910-22</b>  <b>Quantity: 1</b></p>		<p><b>Velcro Head Restraint Kit</b>  <b>Part # 903-0</b>  <b>Quantity: 1</b></p>
	<p><b>Booster Seat</b>  <b>Part # 1000196</b>  <b>Quantity: 1</b>  <b>Available on request</b></p>		<p><b>GeoCal Fixture</b>  <b>Part # 14-1-0</b>  <b>Quantity: 1</b></p>

	<p><b>Foot Stool</b>  <b>Part # 1000197</b>  <b>Quantity: 1</b></p>		<p><b>QA Phantom</b>  <b>Part # 13-00</b>  <b>Quantity: 1</b></p>
	<p><b>Chin Cup</b>  <b>Part # 9140-0026-0006</b>  <b>Quantity: 1</b></p>		<p><b>Water Jar Phantom</b>  <b>Part # 1000224</b>  <b>Quantity: 1</b></p>
	<p><b>Cable Clips</b>  <b>Part # 101-6</b>  <b>Quantity: 6</b></p>		<p><b>Foam Disk</b>  <b>Part # 1000323</b>  <b>Quantity: 1</b></p>
	<p><b>Chair Calibration Fixture</b>  <b>Part # 26-16</b>  <b>Quantity: 1</b></p>		<p><b>Platform Assembly</b>  <b>Part # 14-4-0</b>  <b>Quantity: 1</b></p>
	<p><b>Chin Rest Slide, Straight</b>  <b>Part # 36-1-0</b>  <b>Quantity: 1</b></p>		<p><b>Handswitch (optional)</b>  <b>Part # 1.010.3959</b>  <b>Quantity: 1</b></p>

## PAN Scan Components

	<p><b>Bite Tip Holder</b>  <b>Part # 980220</b>  <b>Quantity: 2</b></p>		<p><b>PAN Head Holder</b>  <b>Part # 33-0</b>  <b>Quantity: 1</b></p>
	<p><b>Position Alignment Tool</b>  <b>Part # 33-19</b>  <b>Quantity: 1</b></p>		<p><b>Bite Tip</b>  <b>Part # 26-15</b>  <b>Quantity: 25</b></p>
	<p><b>Pan Phantom</b>  <b>Part # 12-0</b>  <b>Quantity: 1</b></p>		<p><b>Chin Rest</b>  <b>Part # 26-12</b>  <b>Quantity: 1</b></p>

## Equipment Standards

The scanner was tested and/or evaluated against and found compliant to the following standards/requirements:

ANSI/AAMI ES60601-1	IEC 60601-1-4	IEC 60601-2-44
IEC 60601-1	IEC 60601-1-6	IEC 62366
IEC 60601-1-1	IEC 60601-2-7	IEC 60825-1
IEC 60601-1-2	IEC 60601-2-28	CAN/CSA STD C22.2 No. 60601-1
IEC 60601-1-3	IEC 60601-2-32	CAN/CSA STD C22.2 No. 601.1-M90

Complies with ME Equipment for Dental Extra-Oral Radiography i-CAT FLX  
IEC 60601-2-63:2012

## Equipment Class

Protection against electric shock: Class I  
Applied part has degree of protection against electric shock: Class B  
Class of equipment against ingress of liquids: Ordinary Equipment, IPX0  
Radiated emissions: Class B

## Equipment Cables

The following table lists cables to be used with the scanner.



---

**CAUTION**

Use supplied cables only. The use of an accessory, transducer, or cable with the scanner other than those specified may result in increased emissions or decreased immunity of the scanner.

---

Description	Length	Shielding	Ferrite	Connection	
				From	To
AC Power Cable	12 ft	None	None	AC Power Source	Scanner AC Power Input
Ethernet Cable	50 ft	None	Yes	Scanner Controller	Ethernet Port on Scanner
Controller Cable	50 ft	None	None	Pendant Controller/E-stop	Controller Cable Port on Scanner
Chair Adjust Cable	12 ft	None	None	Chair Adjust Port on Back of Chair	Chair Adjust Port on Scanner
Patient E-Stop Cable	5 ft	None	None	Patient E-Stop Port	Patient E-Stop Controller
Interlock Cable	50 ft	None	None	Interlock Cable Port	Unterminated

## Manufacturer's Declaration

The i-CAT FLX, classified as Medical Electrical Equipment, requires special precautions regarding EMC and must be installed and put into service according to the EMC information provided.

Portable and mobile RF communications equipment can effect Medical Electrical Equipment. The i-CAT FLX complies with EMC requirements when used with the cables and accessories supplied with the product. The use of accessories, transducers and cables other than those sold by ISI and specified as replacement parts for internal components, may result in increased emissions or decreased immunity of the i-CAT FLX.



**CAUTION**

- Do not use any extension cords which are not provided with the scanner. Be aware that multiple portable socket outlets or extension cords are not to be connected to the scanner. Do not connect any items or equipment to this scanner which are not part of the scanner.
  - The i-CAT FLX should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the i-CAT FLX should be observed to verify normal operation in the configuration in which it will be used.
- 


Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The i-CAT FLX is intended for use in the electromagnetic environment specified below. The customer or the user of the i-CAT FLX should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The i-CAT FLX uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.  The i-CAT FLX is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The i-CAT FLX is intended for use in the electromagnetic environment. The customer or the user of the i-CAT FLX should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD)  IEC 61000-4-2	+/-6 kV contact  +/-8 kV air	+/-2, 4 & 6 kV contact  +/-2, 4 & 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst  IEC 61000-4-4	+/-2 kV for power supply lines  +/-1 kV for input/output lines	+/-2 kV for power supply lines  +/-1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge  IEC 61000-4-5	+/-1 kV line(s) to line(s)  +/-2 kV line(s) to earth	+/-0.5 & 1 kV differential mode  +/-0.5, 1 & 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The i-CAT FLX is intended for use in the electromagnetic environment. The customer or the user of the i-CAT FLX should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines  IEC 61000-4-11	$<5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 0.5 cycle  $40\% U_T$ ( $60\%$ dip in $U_T$ ) for 5 cycles  $70\% U_T$ ( $30\%$ dip in $U_T$ ) for 25 cycles  $<5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 5 sec	$<5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 0.5 cycle  $40\% U_T$ ( $60\%$ dip in $U_T$ ) for 5 cycles  $70\% U_T$ ( $30\%$ dip in $U_T$ ) for 25 cycles  $<5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the i-CAT FLX requires continued operation during power mains interruptions, it is recommended that the i-CAT FLX be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field  IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
<b>NOTE:</b> $U_T$ is the a.c. mains voltage prior to application of the test level.			



Guidance and Manufacturer's Declaration - Electromagnetic Emissions			
The i-CAT FLX is intended for use in the electromagnetic environment. The customer or the user of the i-CAT FLX should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF  IEC 61000-4-6	3 Vrms  150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the i-CAT FLX, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance:</b>  $d = 1,2\sqrt{P}$

Guidance and Manufacturer's Declaration - Electromagnetic Emissions			
The i-CAT FLX is intended for use in the electromagnetic environment. The customer or the user of the i-CAT FLX should ensure that it is used in such an environment.			
Radiated RF  IEC 61000-4-3	3 V/m  80 MHz to 2.5 GHz	3 V/m	<div><math display="block">d = 1,2\sqrt{P}</math>80 MHz to 800 MHz</div> <div><math display="block">d = 2,3\sqrt{P}</math>800 MHz to 2.5 GHz</div> <div>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</div> <div>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></div> <div>Interference may occur in the vicinity of equipment marked with the following symbol:</div> <div></div>
<p>Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the i-CAT FLX is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the i-CAT FLX.</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

**Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the i-CAT FLX**

The i-CAT FLX is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the i-CAT FLX can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the i-CAT FLX as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation Distance according to Frequency of Transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.74
1	1.2	1.2	2.3
10	3.8	3.8	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## Acknowledgements

SmartScan STUDIO software makes use of the following open source projects. Source code is available on request.

Library Product Name	Homepage	License
Qt	<a href="http://qt.digia.com/">http://qt.digia.com/</a>	LGPL v2.1 ( <a href="http://www.gnu.org/licenses/lgpl-2.1.html">http://www.gnu.org/licenses/lgpl-2.1.html</a> )
Qt Service	<a href="http://qt.gitorious.org/qt-solutions">qt.gitorious.org/qt-solutions</a>	LGPL v2.1 ( <a href="http://www.gnu.org/licenses/lgpl-2.1.html">http://www.gnu.org/licenses/lgpl-2.1.html</a> )
0mq	<a href="http://www.zeromq.org">www.zeromq.org</a>	LGPL v3 ( <a href="http://www.gnu.org/copyleft/lesser.html">http://www.gnu.org/copyleft/lesser.html</a> )
QJson	<a href="http://qjson.sourceforge.net">qjson.sourceforge.net</a>	LGPL v2.1 ( <a href="http://www.gnu.org/licenses/lgpl-2.1.html">http://www.gnu.org/licenses/lgpl-2.1.html</a> )
jQuery	<a href="http://jquery.com">jquery.com</a>	MIT License ( <a href="http://opensource.org/licenses/MIT">http://opensource.org/licenses/MIT</a> )
DCMTK	<a href="http://dcmktk.org">dcmktk.org</a>	BSD ( <a href="http://opensource.org/licenses/bsd-license.php">http://opensource.org/licenses/bsd-license.php</a> )
JSON.NET	<a href="http://json.codeplex.com">json.codeplex.com</a>	MIT License ( <a href="http://opensource.org/licenses/MIT">http://opensource.org/licenses/MIT</a> )
libqxt	<a href="http://libqxt.org">libqxt.org</a>	LGPL v2.1 ( <a href="http://www.gnu.org/licenses/lgpl-2.1.html">http://www.gnu.org/licenses/lgpl-2.1.html</a> )
log4cplus	<a href="http://log4cplus.sourceforge.net">log4cplus.sourceforge.net</a>	Apache Software License 2.0 ( <a href="http://www.apache.org/licenses/LICENSE-2.0.html">http://www.apache.org/licenses/LICENSE-2.0.html</a> )
log4net	<a href="http://logging.apache.org/log4net">logging.apache.org/log4net</a>	Apache Software License 2.0 ( <a href="http://www.apache.org/licenses/LICENSE-2.0.html">http://www.apache.org/licenses/LICENSE-2.0.html</a> )
QuaZIP	<a href="http://quazip.sourceforge.net">quazip.sourceforge.net</a>	LGPL 2.0 ( <a href="http://www.gnu.org/licenses/old-licenses/lgpl-2.0.html">http://www.gnu.org/licenses/old-licenses/lgpl-2.0.html</a> )

Library Product Name	Homepage	License
Firebird	<a href="http://www.firebirdsql.org">www.firebirdsql.org</a>	IPL ( <a href="http://www.firebirdsql.org/en/interbase-public-license/">http://www.firebirdsql.org/en/interbase-public-license/</a> ) IDPL ( <a href="http://www.firebirdsql.org/en/initial-developer-s-public-license-version-1-0/">http://www.firebirdsql.org/en/initial-developer-s-public-license-version-1-0/</a> )
openssl	<a href="http://www.openssl.org">www.openssl.org</a>	openssl ( <a href="http://www.openssl.org/source/license.html">http://www.openssl.org/source/license.html</a> )



# *Appendix* **C** *Radiation Information*

## ***Recommended Operating Requirements***

Local agencies or government bodies or international standards may dictate requirements for installation of the scanner in order to protect personnel and the public from exposure from the radiological output of the scanner. Consult your local agencies, government bodies, or international standards for actual requirements which apply.

It is recommended that a **qualified Physicist or Radiologist** determine where appropriate, the applicable lead shielding to be installed in the area around the scanner equipment. Below are some other common requirements that may apply to your location:

- The scanner controller and X-ray operator should be located behind a properly shielded permanent barrier. A viewing window (or alternative method such as a mounted mirror) should be present to enable the X-ray operator to view the patient and operate the computer while the exposure is present.
- Operators should consider the use of a lead apron to protect the anatomical areas of the medical personnel working in the areas exposed to radiation.
- The operator control box and scanner controller shall be located within 1 meter [3.28 ft] from a door. If not, an interlocked door may be required.
- A room door may be required.
- Radiation warning signs may be required next to the entrance to the room.
- A warning light may be required by the entrance to the room.
- A shielding plan should be performed where the scanner is being installed. Some local agencies or government bodies require that a shielding plan be conducted by a **qualified Physicist or Radiologist** and a copy of the shielding plan be submitted and approved prior to installation of the scanner.
- An area radiation survey by a **qualified Physicist or Radiologist** may then be required within 30 days of initial clinical use of the scanner. This survey may be required to be submitted to the local agency or government body.
- An annual radiation survey may be typically required. This survey is typically required to be submitted to the local agency or government body.
- A phantom or patients may be used for scanner training. Employees of the facility may not be used for this training.
- The scanner shall be registered with the local agency or government body.

## Scan Times and Settings

**NOTE:** Scan times and settings are preselected and fixed. Scan Time has no affect on electrical power output.

**Linearity of Radiation Output:** <.025 COV

Type	kV	mA	Scan Time (seconds)	Exposure Time (seconds)	mAs	DAP (mGy <sup>2</sup> cm <sup>2</sup> )
3D Ceph	120	5	8.9	3.7	18.54	623.9
Quick Scan	120	5	4.8	2.0	10.11	349.4
Quick Scan+	90	3	4.8	2.0	6.1	99.2
HD	120	5	26.9	7.4	37.07	1257
Quick Scan HD	120	5	14.7	4.1	20.27	659.9
Expanded Standard	120	5	8.9	3.7	18.54	458.6
Expanded Enhanced	120	5	17.8	7.4	37.10	877.6
PAN Large	94	5	20	20	100	146.4
PAN Small	84	5	18.3	18.3	91.5	91

## Scatter Radiation

The direct and scattered beams can produce serious bodily injuries to patients and persons in the surrounding area. Adequate precautions must always be taken to avoid or reduce exposure to the useful beam, as well as scattered radiation.

### Conditions of Operation

All data was acquired using two Technical Associates Mark V integrating ion chamber meters. The data was acquired in concentric circles of radii listed in table below. A 16 cm AAPM head phantom was placed within the beam to act as the scattering agent. The center of the ion chamber was placed at the same height as the center of the beam, which was verified to be the location of highest scatter.

Locations listed in the table are for 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. Looking out from the scanner, 0° was located directly in front.



**Mode: 16 D x 13 3D Standard 0.4mm voxel**

**Time (s): 8.9 scan / 3.7 beam Diameter: 16 mA: 5**

**kVp: 120**

**mAs: 18.54**

Location	Distance in Feet [meter]	Exposure (mR)	Exposure ( $\mu$ R)	Exposure $\mu$ R/mAs	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
<b>0°</b>	3 [0.91m]	0.470	470.0	25.35	4.70	11.75	23.50
	6 [1.82m]	0.120	120.0	6.47	1.20	3.00	6.00
	9 [2.73m]	0.052	52.2	2.81	0.52	1.30	2.61
<b>45°</b>	3 [0.91m]	0.453	453.0	24.43	4.53	11.33	22.65
	6 [1.82m]	0.114	114.0	6.15	1.14	2.85	5.70
	9 [2.73m]	0.050	50.3	2.71	0.50	1.26	2.51
<b>90°</b>	3 [0.91m]	0.412	412.0	22.22	4.12	10.30	20.60
	6 [1.82m]	0.098	98.0	5.29	0.98	2.45	4.90
	9 [2.73m]	0.046	45.7	2.47	0.46	1.14	2.29
<b>135°</b>	3 [0.91m]	0.346	346.0	18.66	3.46	8.65	17.30
	6 [1.82m]	0.087	86.5	4.67	0.87	2.16	4.33
	9 [2.73m]	0.038	38.4	2.07	0.38	0.96	1.92
<b>180°</b>	3 [0.91m]	0.393	393.0	21.20	3.93	9.83	19.65
	6 [1.82m]	0.098	98.3	5.30	0.98	2.46	4.91
	9 [2.73m]	0.044	43.6	2.35	0.44	1.09	2.18
<b>225°</b>	3 [0.91m]	0.342	342.0	18.45	3.42	8.55	17.10
	6 [1.82m]	0.086	85.5	4.61	0.86	2.14	4.28
	9 [2.73m]	0.038	38.0	2.05	0.38	0.95	1.90
<b>270°</b>	3 [0.91m]	0.382	382.0	20.60	3.82	9.55	19.10
	6 [1.82m]	0.103	103.0	5.56	1.03	2.58	5.15
	9 [2.73m]	0.042	42.4	2.29	0.42	1.06	2.12
<b>315°</b>	3 [0.91m]	0.490	490.0	26.43	4.90	12.25	24.50
	6 [1.82m]	0.115	115.0	6.20	1.15	2.88	5.75
	9 [2.73m]	0.054	54.4	2.93	0.54	1.36	2.72
<b>54 cm above</b>		0.067	67.0	3.61	0.67	1.68	3.35
<b>3 feet below</b>		0.304	304.0	16.40	3.04	7.60	15.20

**Mode: 16 D x 13 3D****Quick Scan****Time (s): 4.8 scan / 2.0 beam****Diameter: 16 mA: 5****kVp: 120****mAs: 10.11**

Location	Distance in Feet [meter]	Exposure (mR)	Exposure ( $\mu$ R)	Exposure $\mu$ R/mAs	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
<b>0°</b>	3 [0.91m]	0.244	244.0	24.13	2.44	6.10	12.20
	6 [1.82m]	0.065	65.0	6.43	0.65	1.63	3.25
	9 [2.73m]	0.027	27.1	2.68	0.27	0.68	1.35
<b>45°</b>	3 [0.91m]	0.246	246.0	24.33	2.46	6.15	12.30
	6 [1.82m]	0.063	63.0	6.23	0.63	1.58	3.15
	9 [2.73m]	0.027	27.3	2.70	0.27	0.68	1.37
<b>90°</b>	3 [0.91m]	0.254	254.0	25.12	2.54	6.35	12.70
	6 [1.82m]	0.064	63.5	6.28	0.64	1.59	3.18
	9 [2.73m]	0.028	28.2	2.79	0.28	0.70	1.41
<b>135°</b>	3 [0.91m]	0.220	220.0	21.76	2.20	5.50	11.00
	6 [1.82m]	0.055	55.0	5.44	0.55	1.38	2.75
	9 [2.73m]	0.024	24.4	2.42	0.24	0.61	1.22
<b>180°</b>	3 [0.91m]	0.229	229.0	22.65	2.29	5.73	11.45
	6 [1.82m]	0.057	57.3	5.66	0.57	1.43	2.86
	9 [2.73m]	0.025	25.4	2.51	0.25	0.64	1.27
<b>225°</b>	3 [0.91m]	0.187	187.0	18.50	1.87	4.68	9.35
	6 [1.82m]	0.047	46.8	4.62	0.47	1.17	2.34
	9 [2.73m]	0.021	20.8	2.05	0.21	0.52	1.04
<b>270°</b>	3 [0.91m]	0.184	184.0	18.20	1.84	4.60	9.20
	6 [1.82m]	0.054	54.0	5.34	0.54	1.35	2.70
	9 [2.73m]	0.020	20.4	2.02	0.20	0.51	1.02
<b>315°</b>	3 [0.91m]	0.240	240.0	23.74	2.40	6.00	12.00
	6 [1.82m]	0.055	55.0	5.44	0.55	1.38	2.75
	9 [2.73m]	0.027	26.6	2.64	0.27	0.67	1.33
<b>54 cm above</b>		0.039	39.0	3.86	0.39	0.98	1.95
<b>3 feet below</b>		0.166	166.0	16.42	1.66	4.15	8.30

**Mode: 16 D x 13 3D****Quick Scan+****Time (s): 4.8 scan / 2.0 beam****Diameter: 16 mA: 3****kVp: 90****mAs: 6.1**

Location	Distance in Feet [meter]	Exposure (mR)	Exposure ( $\mu$ R)	Exposure $\mu$ R/mAs	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
<b>0°</b>	3 [0.91m]	0.049	49.0	8.03	0.49	1.23	2.45
	6 [1.82m]	0.011	11.0	1.80	0.11	0.28	0.55
	9 [2.73m]	0.005	5.4	0.89	0.05	0.14	0.27
<b>45°</b>	3 [0.91m]	0.050	50.0	8.20	0.50	1.25	2.50
	6 [1.82m]	0.011	11.4	1.87	0.11	0.29	0.57
	9 [2.73m]	0.006	5.6	0.91	0.06	0.14	0.28
<b>90°</b>	3 [0.91m]	0.053	53.0	8.69	0.53	1.33	2.65
	6 [1.82m]	0.013	13.3	2.17	0.13	0.33	0.66
	9 [2.73m]	0.006	5.9	0.96	0.06	0.15	0.29
<b>135°</b>	3 [0.91m]	0.047	47.0	7.70	0.47	1.18	2.35
	6 [1.82m]	0.012	11.8	1.93	0.12	0.29	0.59
	9 [2.73m]	0.005	5.2	0.86	0.05	0.13	0.26
<b>180°</b>	3 [0.91m]	0.048	48.0	7.87	0.48	1.20	2.40
	6 [1.82m]	0.012	12.0	1.97	0.12	0.30	0.60
	9 [2.73m]	0.005	5.3	0.87	0.05	0.13	0.27
<b>225°</b>	3 [0.91m]	0.039	39.0	6.39	0.39	0.98	1.95
	6 [1.82m]	0.010	9.8	1.60	0.10	0.24	0.49
	9 [2.73m]	0.004	4.3	0.71	0.04	0.11	0.22
<b>270°</b>	3 [0.91m]	0.040	40.0	6.56	0.40	1.00	2.00
	6 [1.82m]	0.010	10.0	1.64	0.10	0.25	0.50
	9 [2.73m]	0.004	4.4	0.73	0.04	0.11	0.22
<b>315°</b>	3 [0.91m]	0.053	53.0	8.69	0.53	1.33	2.65
	6 [1.82m]	0.013	13.3	2.17	0.13	0.33	0.66
	9 [2.73m]	0.006	5.9	0.96	0.06	0.15	0.29
<b>54 cm above</b>		0.001	1.0	0.16	0.01	0.03	0.05
<b>3 feet below</b>		0.033	33.0	5.41	0.33	0.83	1.65

**Mode: 16 D x 13 3D****HD****Time (s): 26.9 scan / 7.4 beam Diameter: 16 mA: 5****kVp: 120****mAs: 37.07**

Location	Distance in Feet [meter]	Exposure (mR)	Exposure ( $\mu$ R)	Exposure $\mu$ R/mAs	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
<b>0°</b>	3 [0.91m]	0.944	944.0	25.47	9.44	23.60	47.20
	6 [1.82m]	0.240	240.0	6.47	2.40	6.00	12.00
	9 [2.73m]	0.105	104.8	2.83	1.05	2.62	5.24
<b>45°</b>	3 [0.91m]	0.909	909.0	24.52	9.09	22.73	45.45
	6 [1.82m]	0.230	230.0	6.20	2.30	5.75	11.50
	9 [2.73m]	0.101	100.9	2.72	1.01	2.52	5.04
<b>90°</b>	3 [0.91m]	0.830	830.0	22.39	8.30	20.75	41.50
	6 [1.82m]	0.208	207.5	5.60	2.08	5.19	10.38
	9 [2.73m]	0.092	92.1	2.49	0.92	2.30	4.61
<b>135°</b>	3 [0.91m]	0.688	688.0	18.56	6.88	17.20	34.40
	6 [1.82m]	0.172	172.0	4.64	1.72	4.30	8.60
	9 [2.73m]	0.076	76.4	2.06	0.76	1.91	3.82
<b>180°</b>	3 [0.91m]	0.799	799.0	21.55	7.99	19.98	39.95
	6 [1.82m]	0.200	199.8	5.39	2.00	4.99	9.99
	9 [2.73m]	0.089	88.7	2.39	0.89	2.22	4.43
<b>225°</b>	3 [0.91m]	0.684	684.0	18.45	6.84	17.10	34.20
	6 [1.82m]	0.171	171.0	4.61	1.71	4.28	8.55
	9 [2.73m]	0.076	75.9	2.05	0.76	1.90	3.80
<b>270°</b>	3 [0.91m]	0.734	734.0	19.80	7.34	18.35	36.70
	6 [1.82m]	0.205	205.0	5.53	2.05	5.13	10.25
	9 [2.73m]	0.081	81.5	2.20	0.81	2.04	4.07
<b>315°</b>	3 [0.91m]	1.085	1085.0	29.27	10.85	27.13	54.25
	6 [1.82m]	0.235	235.0	6.34	2.35	5.88	11.75
	9 [2.73m]	0.120	120.4	3.25	1.20	3.01	6.02
<b>54 cm above</b>		0.129	129.0	3.48	1.29	3.23	6.45
<b>3 feet below</b>		0.604	604.0	16.29	6.04	15.10	30.20

**Mode: 16 D x 13 3D****Quick Scan HD****Time (s): 14.7 scan / 4.1 beam Diameter: 16 mA: 5****kVp: 120****mAs: 20.27**

Location	Distance in Feet [meter]	Exposure (mR)	Exposure ( $\mu$ R)	Exposure $\mu$ R/mAs	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
<b>0°</b>	3 [0.91m]	0.495	495.0	24.42	4.95	12.38	24.75
	6 [1.82m]	0.137	137.0	6.76	1.37	3.43	6.85
	9 [2.73m]	0.055	54.9	2.71	0.55	1.37	2.75
<b>45°</b>	3 [0.91m]	0.492	492.0	24.27	4.92	12.30	24.60
	6 [1.82m]	0.129	129.0	6.36	1.29	3.23	6.45
	9 [2.73m]	0.055	54.6	2.69	0.55	1.37	2.73
<b>90°</b>	3 [0.91m]	0.508	508.0	25.06	5.08	12.70	25.40
	6 [1.82m]	0.127	127.0	6.27	1.27	3.18	6.35
	9 [2.73m]	0.056	56.4	2.78	0.56	1.41	2.82
<b>135°</b>	3 [0.91m]	0.442	442.0	21.81	4.42	11.05	22.10
	6 [1.82m]	0.111	111.0	5.48	1.11	2.78	5.55
	9 [2.73m]	0.049	49.1	2.42	0.49	1.23	2.45
<b>180°</b>	3 [0.91m]	0.466	466.0	22.99	4.66	11.65	23.30
	6 [1.82m]	0.117	116.5	5.75	1.17	2.91	5.83
	9 [2.73m]	0.052	51.7	2.55	0.52	1.29	2.59
<b>225°</b>	3 [0.91m]	0.376	376.0	18.55	3.76	9.40	18.80
	6 [1.82m]	0.094	94.0	4.64	0.94	2.35	4.70
	9 [2.73m]	0.042	41.7	2.06	0.42	1.04	2.09
<b>270°</b>	3 [0.91m]	0.376	376.0	18.55	3.76	9.40	18.80
	6 [1.82m]	0.109	109.0	5.38	1.09	2.73	5.45
	9 [2.73m]	0.042	41.7	2.06	0.42	1.04	2.09
<b>315°</b>	3 [0.91m]	0.510	510.0	25.16	5.10	12.75	25.50
	6 [1.82m]	0.121	121.0	5.97	1.21	3.03	6.05
	9 [2.73m]	0.057	56.6	2.79	0.57	1.42	2.83
<b>54 cm above</b>		0.068	67.6	3.34	0.68	1.69	3.38
<b>3 feet below</b>		0.317	316.7	15.62	3.17	7.92	15.84

**Mode: 23 D x17 3D**      **Expanded - Standard**  
**Time (s): 8.9 scan / 3.7 beam**    **Diameter: 23    mA: 5**  
**kVp: 120**      **mAs: 18.54**

Location	Distance in Feet [meter]	Exposure (mR)	Exposure ( $\mu$ R)	Exposure $\mu$ R/mAs	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
<b>0°</b>	3 [0.91m]	0.333	333.0	17.96	3.33	8.33	16.65
	6 [1.82m]	0.086	86.0	4.64	0.86	2.15	4.30
	9 [2.73m]	0.037	37.0	1.99	0.37	0.92	1.85
<b>45°</b>	3 [0.91m]	0.333	333.0	17.96	3.33	8.33	16.65
	6 [1.82m]	0.086	86.0	4.64	0.86	2.15	4.30
	9 [2.73m]	0.037	37.0	1.99	0.37	0.92	1.85
<b>90°</b>	3 [0.91m]	0.321	321.0	17.31	3.21	8.03	16.05
	6 [1.82m]	0.080	80.3	4.33	0.80	2.01	4.01
	9 [2.73m]	0.036	35.6	1.92	0.36	0.89	1.78
<b>135°</b>	3 [0.91m]	0.307	307.0	16.56	3.07	7.68	15.35
	6 [1.82m]	0.077	76.8	4.14	0.77	1.92	3.84
	9 [2.73m]	0.034	34.1	1.84	0.34	0.85	1.70
<b>180°</b>	3 [0.91m]	0.384	384.0	20.71	3.84	9.60	19.20
	6 [1.82m]	0.096	96.0	5.18	0.96	2.40	4.80
	9 [2.73m]	0.043	42.6	2.30	0.43	1.07	2.13
<b>225°</b>	3 [0.91m]	0.302	302.0	16.29	3.02	7.55	15.10
	6 [1.82m]	0.076	75.5	4.07	0.76	1.89	3.78
	9 [2.73m]	0.034	33.5	1.81	0.34	0.84	1.68
<b>270°</b>	3 [0.91m]	0.322	322.0	17.37	3.22	8.05	16.10
	6 [1.82m]	0.081	80.5	4.34	0.81	2.01	4.03
	9 [2.73m]	0.036	35.7	1.93	0.36	0.89	1.79
<b>315°</b>	3 [0.91m]	0.412	412.0	22.22	4.12	10.30	20.60
	6 [1.82m]	0.103	103.0	5.56	1.03	2.58	5.15
	9 [2.73m]	0.046	45.7	2.47	0.46	1.14	2.29
<b>54 cm above</b>		0.069	69.0	3.72	0.69	1.73	3.45
<b>3 feet below</b>		0.229	229.0	12.35	2.29	5.73	11.45

**Mode: 23 D x17 3D**      **Expanded - Enhanced**  
**Time (s): 17.8 scan / 7.4 beam**   **Diameter: 23**   **mA: 5**  
**kVp: 120**      **mAs: 37.10**

Location	Distance in Feet [meter]	Exposure (mR)	Exposure ( $\mu$ R)	Exposure $\mu$ R/mAs	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
<b>0°</b>	3 [0.91m]	0.672	672.0	18.11	6.72	16.80	33.60
	6 [1.82m]	0.177	177.0	4.77	1.77	4.43	8.85
	9 [2.73m]	0.075	74.6	2.01	0.75	1.86	3.73
<b>45°</b>	3 [0.91m]	0.664	664.0	17.90	6.64	16.60	33.20
	6 [1.82m]	0.174	174.0	4.69	1.74	4.35	8.70
	9 [2.73m]	0.074	73.7	1.99	0.74	1.84	3.69
<b>90°</b>	3 [0.91m]	0.644	644.0	17.36	6.44	16.10	32.20
	6 [1.82m]	0.161	161.0	4.34	1.61	4.03	8.05
	9 [2.73m]	0.071	71.5	1.93	0.71	1.79	3.57
<b>135°</b>	3 [0.91m]	0.612	612.0	16.50	6.12	15.30	30.60
	6 [1.82m]	0.153	153.0	4.12	1.53	3.83	7.65
	9 [2.73m]	0.068	67.9	1.83	0.68	1.70	3.40
<b>180°</b>	3 [0.91m]	0.776	776.0	20.92	7.76	19.40	38.80
	6 [1.82m]	0.194	194.0	5.23	1.94	4.85	9.70
	9 [2.73m]	0.086	86.1	2.32	0.86	2.15	4.31
<b>225°</b>	3 [0.91m]	0.599	599.0	16.15	5.99	14.98	29.95
	6 [1.82m]	0.150	149.8	4.04	1.50	3.74	7.49
	9 [2.73m]	0.066	66.5	1.79	0.66	1.66	3.32
<b>270°</b>	3 [0.91m]	0.654	654.0	17.63	6.54	16.35	32.70
	6 [1.82m]	0.170	170.0	4.58	1.70	4.25	8.50
	9 [2.73m]	0.073	72.6	1.96	0.73	1.81	3.63
<b>315°</b>	3 [0.91m]	0.823	823.0	22.18	8.23	20.58	41.15
	6 [1.82m]	0.177	177.0	4.77	1.77	4.43	8.85
	9 [2.73m]	0.091	91.4	2.46	0.91	2.28	4.57
<b>54 cm above</b>		0.138	138.0	3.72	1.38	3.45	6.90
<b>3 feet below</b>		0.458	458.0	12.35	4.58	11.45	22.90

**Mode: 16 D x 13 PAN****Large****Time (s): 20 scan / 20 beam****Diameter: 16 mA: 5****kVp: 94****mAs: 100**

Location	Distance in Feet [meter]	Exposure (mR)	Exposure ( $\mu$ R)	Exposure $\mu$ R/mAs	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
<b>0°</b>	3 [0.91m]	0.130	130.0	1.30	1.30	3.25	6.50
	6 [1.82m]	0.038	38.0	0.38	0.38	0.95	1.90
	9 [2.73m]	0.014	14.4	0.14	0.14	0.36	0.72
<b>45°</b>	3 [0.91m]	0.152	152.0	1.52	1.52	3.80	7.60
	6 [1.82m]	0.035	35.0	0.35	0.35	0.88	1.75
	9 [2.73m]	0.017	16.9	0.17	0.17	0.42	0.84
<b>90°</b>	3 [0.91m]	0.124	124.0	1.24	1.24	3.10	6.20
	6 [1.82m]	0.031	31.0	0.31	0.31	0.78	1.55
	9 [2.73m]	0.014	13.8	0.14	0.14	0.34	0.69
<b>135°</b>	3 [0.91m]	0.172	172.0	1.72	1.72	4.30	8.60
	6 [1.82m]	0.043	43.0	0.43	0.43	1.08	2.15
	9 [2.73m]	0.019	19.1	0.19	0.19	0.48	0.95
<b>180°</b>	3 [0.91m]	0.199	199.0	1.99	1.99	4.98	9.95
	6 [1.82m]	0.050	49.8	0.50	0.50	1.24	2.49
	9 [2.73m]	0.022	22.1	0.22	0.22	0.55	1.10
<b>225°</b>	3 [0.91m]	0.122	122.0	1.22	1.22	3.05	6.10
	6 [1.82m]	0.031	30.5	0.31	0.31	0.76	1.53
	9 [2.73m]	0.014	13.5	0.14	0.14	0.34	0.68
<b>270°</b>	3 [0.91m]	0.066	66.0	0.66	0.66	1.65	3.30
	6 [1.82m]	0.016	16.0	0.16	0.16	0.40	0.80
	9 [2.73m]	0.007	7.3	0.07	0.07	0.18	0.37
<b>315°</b>	3 [0.91m]	0.152	152.0	1.52	1.52	3.80	7.60
	6 [1.82m]	0.034	34.0	0.34	0.34	0.85	1.70
	9 [2.73m]	0.017	16.9	0.17	0.17	0.42	0.84
<b>54 cm above</b>		0.038	38.0	0.38	0.38	0.95	1.90
<b>3 feet below</b>		0.089	89.0	0.89	0.89	2.23	4.45



## Patient Dose

**CTDI<sub>w</sub> - Weighted Computed Tomography Dose Index** - Developed to establish the dose in a phantom to a voxel of tissue from contributions of dose from all slices in a multi-slice protocol. This measurement uses a 100 mm ionization chamber and approximates the dose from the primary beam and slices adjacent in a single scan (single slice). For the measurement to be valid, the X-ray width should be much less than 100 mm. This measure takes into account the sum of 1/3 of the phantom central dose and 2/3 of the peripheral dose. CTDI<sub>w</sub> was not intended to be used for CBCT. As such, this should be considered an approximate value only. Data was collected with a Radcal Model 3036 electrometer connected to a 3 cc CT chamber in a 16 cm AAPM head phantom.

**CTDI Free-air** - Approximated a 100 mm CTDI from a free in air exposure. Included for reference only.

**Mid Scan Dose** - A weighted dose estimate designed to approximate dose in a phantom from a single large width scan or a continuous helical scan. This may be a better measurement for approximating dose for CBCT. This measurement uses a single very small energy compensated solid-state detector. This detector approximates the dose seen by a voxel of tissue from primary beam incident to it, as well as scatter from adjacent areas exposed to the same beam. Data was collected with an RTI Piranha electrometer connected to a 0.3 mm solid state, energy compensated detector in a 16 cm AAPM head phantom.

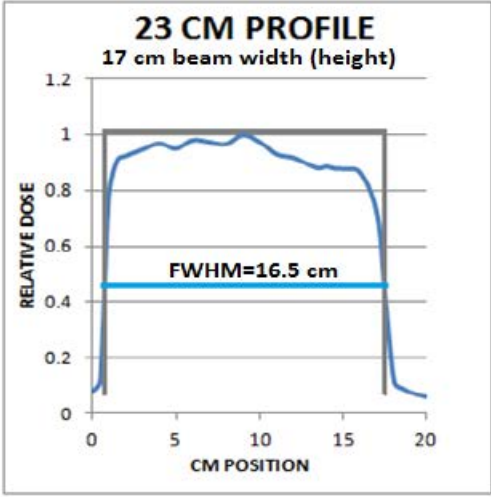
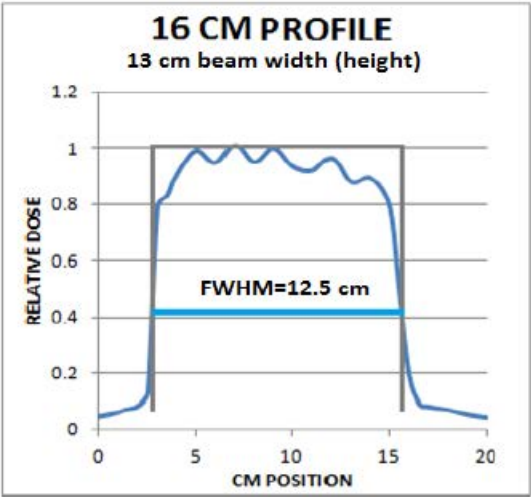
All dose values are in mGy.

Acq. Time (sec)	13 cm			11 cm			10 cm		
	CTDI <sub>w</sub>	CTDI Free air	Mid Scan Dose	CTDI <sub>w</sub>	CTDI Free air	Mid Scan Dose	CTDI <sub>w</sub>	CTDI Free air	Mid Scan Dose
8.9	1.9	2.5	2.1	1.9	2.5	1.9	1.9	2.5	1.9
4.8	1.0	1.3	1.2	1.0	1.3	1.1	1.0	1.3	1.0
4.8 (90 kVp)	0.3	0.4	0.3	0.3	0.4	0.3	0.3	0.3	0.3
26.9	3.8	4.9	4.2	3.9	5.0	3.9	3.6	4.7	3.8
14.7	2.1	2.7	2.1	2.1	2.7	2.0	2.0	2.6	2.1

Acq. Time (sec)	8 cm			6 cm			4 cm		
	CTDI <sub>w</sub>	CTDI Free air	Mid Scan Dose	CTDI <sub>w</sub>	CTDI Free air	Mid Scan Dose	CTDI <sub>w</sub>	CTDI Free air	Mid Scan Dose
8.9	2.0	2.6	1.7	2.0	2.6	1.5	2.1	2.8	1.2
4.8	1.0	1.3	1.0	1.0	1.3	0.8	1.6	2.1	0.7
4.8 (90 kVp)	0.3	0.4	0.3	0.3	0.4	0.2	0.3	0.4	0.2
26.9	4.0	5.2	3.5	4.0	5.2	3.0	4.2	5.5	2.5
14.7	2.1	2.7	1.9	2.1	2.7	1.6	2.2	2.9	1.3

### Dose and Sensitivity Profile

The dose profile for the 16 and 23 cm scans were performed using a 0.3 mm solid state CT probe. Measurements were made at 0.5 and 1 cm intervals across the profile of the beam using an 8.9 second scan. The results were normalized to the maximum value and plotted versus detector position.



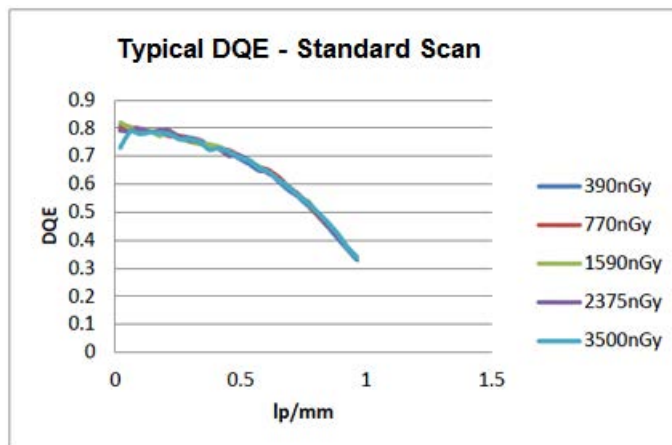
— Sensitivity profile

— Dose profile

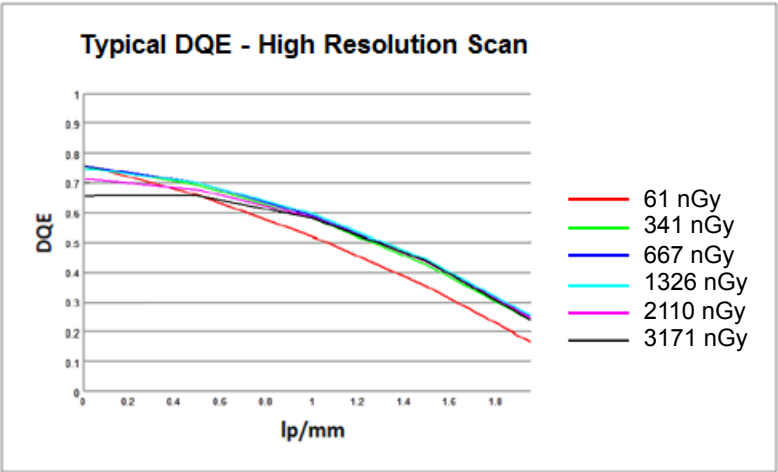
## Detective Quantum Efficiency (DQE)

The following data regarding DQE versus spatial frequency as a function of dose is provided to allow the contribution of the i-CAT FLX to overall imaging performance matrix.

The graph below shows a typical DQE for the 2520DX sensor panel as a function of spatial frequency, for a range of X-ray doses from 390 to 3500 nGy for a standard scan. The curves indicate that there is no significant change in DQE performance going from 390 nGy to 3500 nGy. This implies that the sensor panel operates quantum limited over that dose range, indicating that all photons are being used effectively and that noise does not degrade performance at low doses. The curve also indicates that the device can resolve detail down to 1 line pair per millimeter (lp/mm). This means that the sensor panel exhibits no reduction in resolution over the input dose range from 390 to 3500 nGy.



The graph below shows a typical DQE for the 2520DX sensor panel DQE as a function of spatial frequency, for a range of X-ray doses from 61 to 3171 nGy for a high resolution scan. The curves indicate that there is no significant change in DQE performance going from 61 nGy to 3171 nGy. This implies that the sensor panel operates quantum limited over that dose range, indicating that all photons are being used effectively and that noise does not degrade performance at low doses. The curve also indicates that the device can resolve detail down to 2 line pairs per millimeter (lp/mm) (over all doses). This means that the sensor panel exhibits no reduction in resolution over the input dose range from 61 to 3171 nGy.



***X-ray Tube Assembly***

Nominal X-Ray Tube Voltage	120 kV
Max. Tube Current	7 mA
X-Ray Tube Nominal Anode Input Power	65 W
X-Ray Tube Maximum Anode Heat Content (HU = KvP x mA x Time in Seconds)	30,000 HU
X-Ray Tube Single Load Rating	120kV, 5mA
Max. X-Ray Tube Assembly Heat Content	120K HU
Max. Continuous Heat Dissipation of Tube Assy	65W
High Voltage Supply Requirements	120 VAC at 10 amps
Loading Factors Concerning Leakage Radiation: CT Scan = 120kV 5mA 12 mS x 618 or 309 PAN Scan = 94kV 5mA	

X-ray Tube Data

X-ray Tube Type: SXR 130-15-0.5

Available focal spot size: 0.5

Available target angle: 15°

Anode construction: Vacuum cast copper with tungsten target

Cathode construction: Vacuum tube nickel with tungsten filament

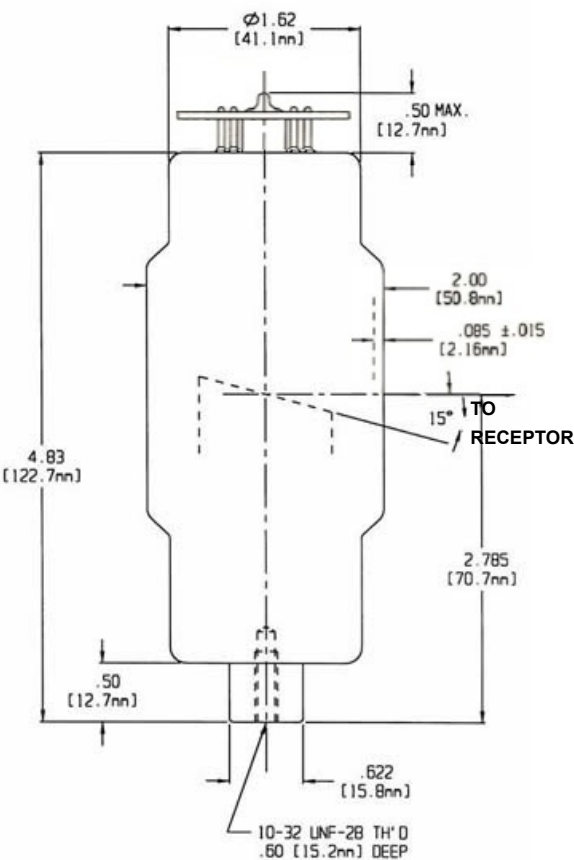
Max. Tube operating voltage: 130 kVp Full wave rectified

Inherent Filtration: 1.1 mm Al equivalent / Glass

Cooling Method: High dielectric transformer oil

Conditioning of Tube Head:

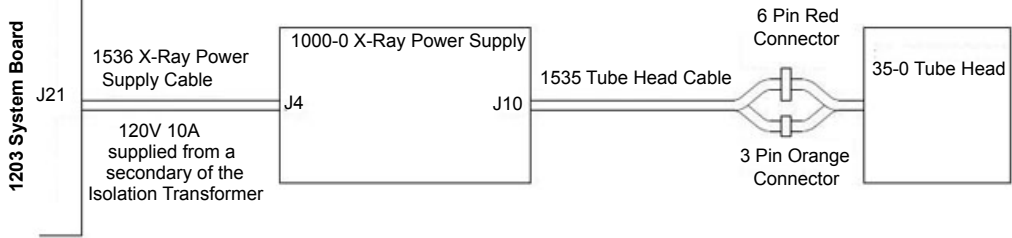
Must be at or above 22°C before first scan.  
Allow scanner to acclimatize for two hours if operating environment was out of range or scanner was stored out of range.



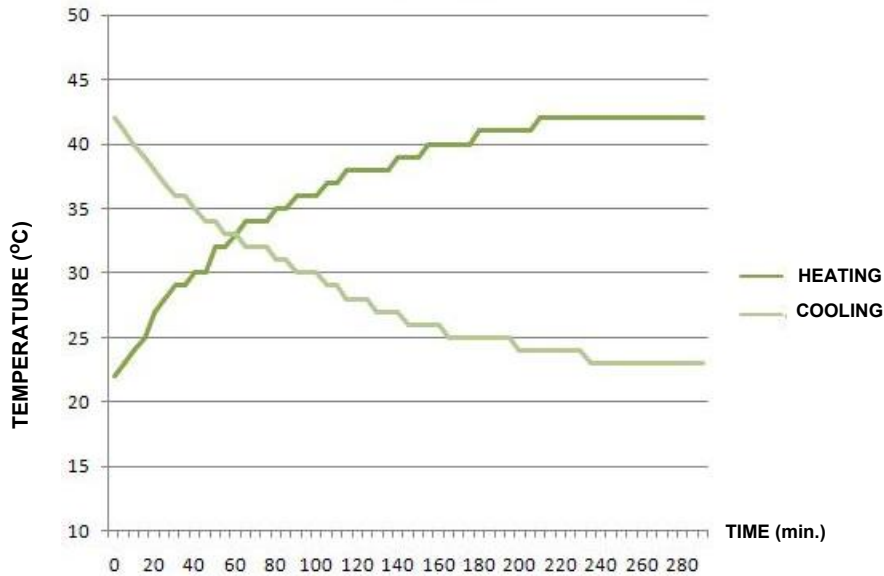
SXR-130-15-0.5  
FOCAL SPOT

X-Ray Tube Voltage	X-Ray Tube Current	Normal Electrical Power
84 kV	5mA	420W
94 kV	5mA	470W
120 kV	5mA	600W

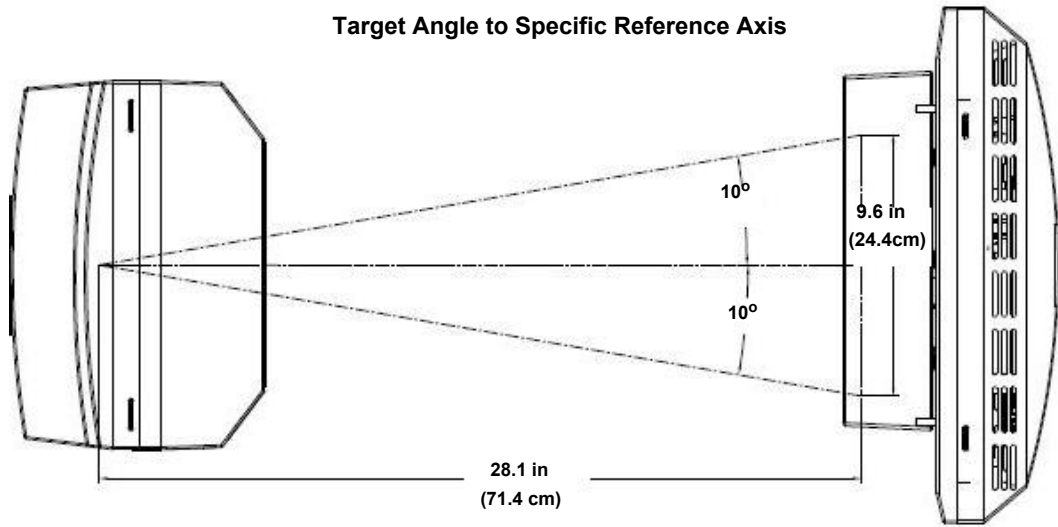
**X-Ray Power Supply Tube Head Assembly Tested  
(no other additional accessories tested)**

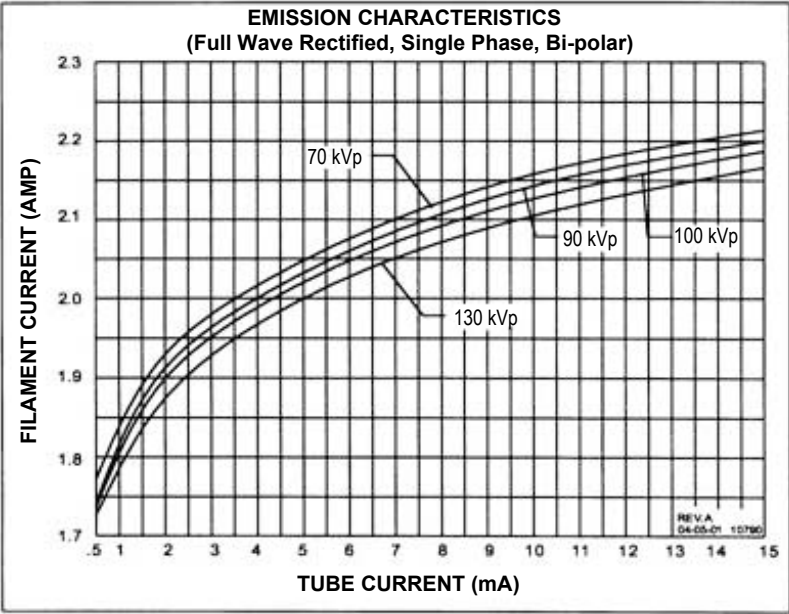


**X-Ray Tube Head Heating and Cooling Chart**

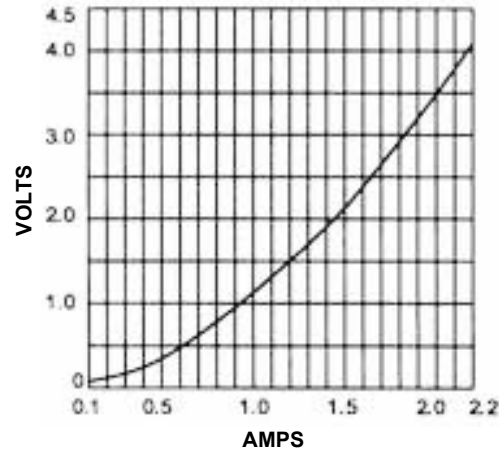


**CONDITIONS FOR X-RAY TUBE HEAD HEATING AND COOLING TEST**  
MACHINE CYCLED IN PAN MODE: 1 SCAN EVERY 5 MINUTES  
PAN MODE SETTINGS: 94KV 5mA 20SEC SCAN  
AMBIENT TEMPERATURE: 22°C

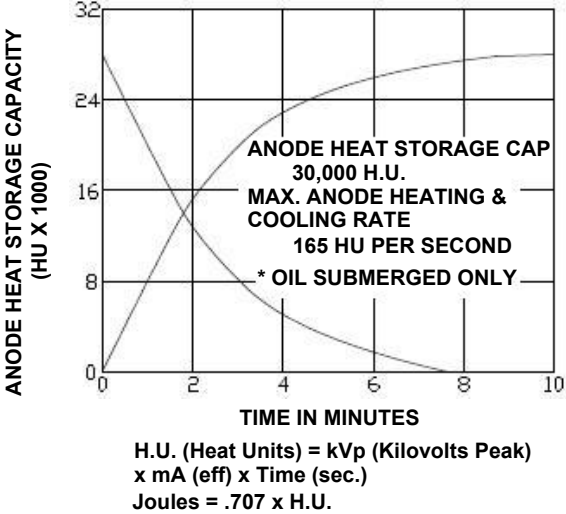




**FILAMENT VOLT/AMPS CHARACTERISTICS:**  
60 Hz AC & DC



**ANODE HEATING/COOLING CURVE**



**SXR-130-15-0.5**







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